

the Cannabis Scientist™

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A person in a red kayak is seen from behind, paddling on vibrant turquoise water. The kayaker is wearing a red cap and a backpack. To the left, a dark, steep cliff face rises from the water, with some water splashing near the kayak. In the distance, more green, forested hills and cliffs are visible under a bright sky with scattered white clouds. The overall scene is one of outdoor adventure and natural beauty.

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When Life Gives You Lemons...

*In the wake of a turbulent 12 months (and with more on the horizon),
make like Kool & The Gang and celebrate good times*

Editorial



Twenty twenty-one has been quite the year. It has somehow both depressed and delighted in almost every possible way (personally, politically, economically, and environmentally) – with the exception of perhaps one special area. Cannabis. On reflection, our plucky plant has fared surprisingly well in the face of another Truly Terrible Year™. Luxembourg became the first EU country to legalize, with over-18s allowed to grow up to four plants for personal use and carry three grams in public (trade in seeds permitted). Further afield, Mexico's Supreme Court decriminalized private recreational use of cannabis by adults, calling the current prohibition “unconstitutional.” In Central America, Panama's national assembly unanimously passed Bill 153 following a five-year struggle, legalizing medical marijuana, with members of the assembly swayed by the initiative's motto, “For a day without pain.” With Germany soon following suit, decriminalizing select sale and consumption rules in a significant drug policy change for the new ruling coalition government.

Industry also made its thoughts on cannabis clear. In recent weeks, Uber Eats Canada made its tentative first steps into the regulated marijuana market by offering a click-and-collect cannabis service, while Amazon doubled down on its efforts to reform the nation's cannabis policy. In June, we reported that the NFL and NFL Players Association announced \$1 million in grant funding to researchers investigating the therapeutic potential of cannabinoids in pain management. In doing so, they made a public statement to the federal government: start funding cannabis research now. And perhaps it will; 2021 also saw the removal of a roadblock to rigorous studies by registering several additional American companies to produce cannabis for medical and scientific purposes. Acceptance has become so widespread that even events as innocuous as the California State Fair, a most wholesome of institutions, has introduced a competitive category for cannabis breeders.

Why does this matter? Because sometimes it pays to look on the bright side. The world may be in flux but there are still wins to be had – so let's celebrate them. Frankly, with the recently identified Omicron variant of concern reminding us that there is more uncertainty ahead, it feels wrong to do anything but keep the glass half full. No matter what happens, the forecast for cannabis appears to remain steadfastly on the up – in no small part because of people like you. Your research is shaping the industry for the better, helping us to understand this wonderful plant and share its benefits with those who need it most. So while you're at it, celebrate yourselves. You deserve it.

Phoebe Harkin
Deputy Editor



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Feel free to contact any one of us:
first.lastname@texerepublishing.com

Content Team

Content Director - Rich Whitworth
Phoebe Harkin (Deputy Editor)

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Content Director - Rich Whitworth

Change of address info@thecannabisscientist.com
Hayley Atiz, Cannabis Scientist, Texere Publishing Limited, Booths Park 1, Chelford Road, Knutsford, Cheshire, WA16 8GS, UK

General enquiries
www.texerepublishing.com | info@thecannabisscientist.com
+44 (0) 1565 745 200 | sales@thecannabisscientist.com

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Easy as C-B-C

Two studies, one phytocannabinoid: is it time we woke up to the wonders of cannabichromene?

Cannabichromene (CBC) may not be the most well-known phytocannabinoid in cannabis, but it has its moments. Take this study investigating its acute post-dose pharmacokinetics (PK) in humans (1).

Researchers analyzed a randomized trial investigating Spectrum Yellow oil – an oral cannabis product containing 20 mg CBD, 0.9 mg Δ^9 -tetrahydrocannabinol (THC), and 1.1 mg CBC, per 1 mL of oil. Plasma CBC concentrations were analyzed by a validated two-dimensional high-performance liquid chromatography–tandem mass spectrometry assay. The results were interesting.

After a single dose and after the final dose, the C_{max} of CBC increased by 1.3–1.8-fold for each twofold increase in dose. Based on the ratio of administered CBD, THC, and CBC to the plasma concentration, the dose of CBD was 18 times higher than the dose of CBC, yet the AUC_{0–t} of CBD was only 6.6–9.8-fold higher than the AUC_{0–t} of CBC; the dose of THC was similar to the dose of CBC, yet THC was quantifiable in fewer plasma samples than was CBC.



The takeaway: CBC may have preferential absorption over CBD and THC when administered together.

But that's not all. Acute respiratory distress syndrome (ARDS) currently has no target-specific treatment, but there is mounting evidence that cannabinoids could offer relief. In an experimental model of ARDS, researchers investigated the potential protective effects of one of cannabis' most abundant nonpsychotropics: that's right, our friend CBC (2). And the data look promising.

"Inhalant CBC protected lung structure, contained excessive cytokine production,

and curtailed inflammatory responses both in lung and blood tissues." Moreover, CBC appears to exert its effects through TRP cation channels, which suggests potential in other inflammatory diseases.

The researchers also note the importance of CBC delivery via inhaler in terms of translational promise: faster onset of action, smaller doses, and better efficacy-to-safety ratio than systemic therapy.

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INFOGRAPHIC

Crime and Punishment

Key takeaways from The Global Drug Policy Index 2021

the Cannabis Scientist

HIGHEST RANKING

- | | | |
|--------|----|----------------|
| 74/100 | #1 | Norway |
| 72/100 | #2 | New Zealand |
| 70/100 | #3 | Portugal |
| 69/100 | #4 | United Kingdom |
| 65/100 | #5 | Australia |



LOWEST RANKING

- | | | |
|--------|-----|-----------|
| 26/100 | #30 | Brazil |
| 28/100 | #29 | Uganda |
| 29/100 | #28 | Indonesia |
| 34/100 | #27 | Kenya |
| 36/100 | #26 | Mexico |



BUSINESS IN BRIEF

*The latest industry news –
in 40 words or less*

- JPMorgan restricts trading of some US cannabis stocks. As of November, clients can no longer make new purchases or short positions in cannabis-related businesses, clients with existing positions can liquidate them.
- US adult-use cannabis sales slip from 2020 pace after lackluster summer; total growth of top five states only 15.9 percent compared with the same period in 2019.
- Increases in arrest rate disparities in states without legalization or decriminalization highlight the need for targeted interventions to address racial injustice, according to investigation.
- As study reports CA\$2.6 billion rise in alcohol and cannabis sales across Canada during pandemic, addiction research scientists call for more resources to deal with associated substance abuse increase.
- American Indian tribes turning to partnerships to secure marijuana business

opportunities, breaking down long standing barriers to Indigenous entrepreneurship in cannabis and hemp industries.



Credit: Pixabay.

- US Department of Veteran Affairs rejects cannabis research despite millions of veterans self-medicating for war-caused ailments; critics claim the move is latest in a long history of stonewalling plant-derived cannabis trials for therapeutic purposes.
- Germany set to decriminalize certain sale and consumption rules of cannabis in a significant drug policy change for the ruling coalition government, following the departure of Angela Merkel.
- Uber Eats Canada offers click-and-collect cannabis service, marking the brand's tentative first steps into the regulated marijuana market.

Baby Brain

Is cannabis use associated with cerebral cortical thickness development during adolescence?

So relaxed laws don't necessarily lead to youth marijuana use - but what about those who do choose to partake? To what extent is this cannabis use associated with cerebral cortical thickness development during adolescence? Well, a worrying amount (1). Unfortunately for young users, the spatial pattern of cannabis-related cortical thinning correlates with a positron emission tomography-assessed map of regions rich in cannabinoid 1 receptors. Interestingly, the imaging findings are also consistent with recent animal research on adolescent THC exposure and prefrontal cortical maturation, which found that adolescent THC exposure resulted in distinct proximate and long-term alterations of dendritic architecture.

The researchers of this study hypothesize that the cannabis-related thinning is underpinned by the same neurobiological phenomenon.

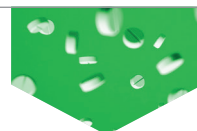
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The **MEDIAN** score was only 48 – and no country got a perfect score (**NORWAY** did best with **74**)



Global inequities, in part due to the legacy of **COLONIALISM**, play a significant role in explaining inequality. These long-term impacts are magnified by a reliance on **STIGMATIZING DRUGS**.



DRUG POLICIES are intrinsically complex, and countries' performance in one dimension of drug policy may not necessarily mirror how well they are doing in another.

Most countries' drug policies are misaligned with their **GOVERNMENTS' PUBLIC HEALTH OBLIGATIONS**, and continue to rely on **CRIMINALIZATION** and police interventions as a form of control.



Credit: Pixabay.

The Future of Device Regulation

In the absence of federal action, states should step up and demand materials and chemistry characterization of cannabis vape devices for the good of the cannabis industry.

By Mark Hubbard, Chief Scientific Officer at Pharma Ed Resources and Canna Pharma 2021

Historically, state governments have pioneered the regulation of public health and safety. In fact, over a century ago, they were the key experiment stations across a broad spectrum of regulatory policy domains, including public health, child labor, and workplace and consumer safety. Fast-forward to today and this state-centric, regulatory-building process is replaying before our eyes in the cannabis industry.

But what will the future of cannabis regulation be? The latest FDA guidance on e-Nicotine devices (ENDs) offers one clue (1). According to the guidance, manufacturers of ENDs will be required to i) produce rigorous materials and chemistry characterization of their product, and ii) conduct stability testing across the product's lifecycle – before gaining commercial approval.

So, what are the implications for the cannabis industry?

For one, we will soon live in a world in which a delivery device in one market sector – tobacco – is subject to the gold standard of safety requirements, while the same device used in another market sector – cannabis – is not. As the saying

goes, “only in America.”

Today, states require testing of cannabis products for many potentially harmful contaminants. And Colorado recently announced it will also require testing of cannabis vape device aerosols for heavy metals contamination beginning 2022 – an industry first (2). But if the devices themselves and their components are not properly characterized and, if necessary, tested for potentially harmful leachables, how can we be certain of their safety?

There can be little doubt that the FDA will eventually extend the same requirements to cannabis delivery devices that are to be imposed on ENDs (of all delivery devices, aerosolizers are ranked as having the highest risk by US regulators (3)). In fact, the FDA is already making moves with its recently drafted guidance on quality assurance for cannabis-derived drug candidates, which explicitly references compendial

literature mandating toxicological risk assessments (including extractables/leachables profiling) of delivery devices and their primary and secondary packaging (4).

The drafts signal that expanded and costly analytical testing requirements are coming to the cannabis delivery device industry – and they are coming fast. But why wait for the shoe to drop? States, in collaboration with industry stakeholders, could initiate materials and chemistry characterization requirements for cannabis vape devices right now. Such requirements – when implemented stepwise with stakeholder input, over a reasonable time frame (years, not months) – could produce lasting benefits for the industry.

I know a woman who used to swear by her vape pen – not anymore. The vape crisis scared her. Now, her trepidation extends to cannabis products generally,

In My View

Experts from across the world share a single strongly held opinion or key idea



not just vapes. If you're reading this, chances are you too know someone who has expressed similar concerns. The crisis tarnished the nascent industry, especially among consumers still uncertain about legal cannabis. Shoring up consumer confidence in cannabis vape products is in the industry's long-term best interest.

Beyond any commercial calculus, state public health officials have a basic responsibility to protect consumer health and safety. That same obligation falls heavily on the cannabis industry. Cannabis industry stakeholders should welcome the same safety and testing requirements of their devices that are soon to be expected for ENDS.

Currently, the cannabis industry enjoys a window of policy making opportunity. Regulatory capacity expands by accretion, with each new layer built upon, and shaped by, pre-existing institutional and political relationships. Act now, and cannabis stakeholders lay practical and moral claim to the regulatory frameworks that they themselves help to build. Wait to act, and the FDA's

eventual involvement surely will be more disruptive to the industry.

There is also a powerful cultural reason to embrace characterization requirements for CBD/THC vape devices. So long as cannabis vape devices are treated differently than other like-products, the cannabis stigma endures. As our nation's history has shown all too painfully, separate has never meant equal.

Over a century ago, the weakness of federal administrative capacity prompted the states to build new and durable regulatory frameworks for many industries. Today, the cannabis industry stands in a similar position vis-à-vis federal authority. Achieving scientifically valid and reproducible methods for characterizing cannabis vape devices will take time and resources. But there is no reason why the industry and its leading scientists – in collaboration with state administrative agencies – cannot begin now to map the regulatory future. Arguably, waiting to do so will only increase the costs to the industry.

Is that a price we're willing to pay?

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From Sea to Shining Sea

European lessons from the US' journey to cannabis legalization

By Mitesh Makwana, Founder and Chairman of AltoVerde

There is no denying that we've seen huge strides in the legalization of cannabis in the last few years. We have effectively watched the birth – and growth – of a new industry. The US legal cannabis industry was estimated at US\$13.6 billion in 2019 – with 340,000 jobs devoted to the handling



of plants, despite the plant being illegal under federal law as a Schedule 1 drug. As of April 2021, 35 states and the District of Columbia have legalized cannabis for medical use – and 16 of those allow adult recreational use

As for Europe, there has been a flurry of activity in mergers and acquisitions involving companies focused on medical cannabis since the beginning of 2019. In total, north of €100 million of new money

has been invested in medical cannabis-focused companies over the past 18 months. Though this represents a sharp increase compared with the period before 2019, Europe is still far from experiencing the growth seen in North America. So, what key lessons can Europe learn from the US if it wants its medical cannabis industry to reach similar heights? Here, I outline four areas of consideration.

I. Legal and regulatory landscape
The US cannabis industry has had to continuously adapt to meet the demands of an ever-changing landscape. Much of this landscape relates to the legality of the drug, with different states implementing different laws regarding the legality, use, distribution, and growth of the substance.

“As a result, cannabis entrepreneurs struggle to start and grow their businesses, while investors are deterred from entering the industry at all.”

Though cannabis remains illegal at the federal level, state-level legalization decisions have allowed the growth of cannabis companies; however, the extremely unpredictable regulatory framework has made the US cannabis industry (understandably) hard to navigate. As a result, cannabis entrepreneurs struggle to start and grow their businesses, while investors are deterred from entering the industry at all.

Even if companies want to establish themselves in a state where cannabis is legal, they must still tackle a myriad of legal and financial barriers – and that’s why many companies have been forced to raise capital from investors in Canada, which has already legalized cannabis and found a suitable structure to facilitate the industry’s growth.

If European governments are to build an efficient, high-growth medical cannabis industry for both companies and investors, they must establish a universal, easily applicable regulatory and

legal framework. (Given the post-Brexit landscape, any framework should also be adopted into UK legislation to avoid cross-border complications.) Europe should also ensure that the industry is accessible to a broader demographic and establish simplified regulations to prevent smaller companies from going bankrupt to the benefit of a monopoly.

II. Regulate taxes appropriately

For the European legal cannabis industry to not only thrive, but drive out the illegal market, taxes must be kept at an affordable level. If taxes and, subsequently, the total cost of legal products are too high, consumers will continue to source from alternative sources and unregulated markets. By August 2018, California fell \$100 million short of its projected annual tax revenue following marijuana legalization. It isn’t a coincidence that California has high marijuana taxes. An eighth-of-an-ounce (approximately 3.5 grams) that would cost \$40 on the black market is around \$70 in stores. Setting a lower tax revenue will serve the legal industry tremendously, attracting new consumers and driving out illegal sellers for good. Once the illegal market dries up, taxes can be re-evaluated to ensure the legal cannabis industry remains sustainable.

In short, Europe should stay clear of 40 percent taxes on medical cannabis – the amount companies in California were charged before reforms. Especially given that levying high taxes on cannabis businesses, rather than on the consumer, can lead to short supply. An earlier iteration of Washington state legislation levied 25 percent tax on cultivators, producers, and retailers – to great success.

III. Scale strategically

Maximizing production is, in and of itself, not a viable strategy. Cannabis

producers must strategically differentiate themselves from their competitors to optimize production and establish a consumer base that will drive their business. By moving away from a trial-and-error model and refining product through scientific research, companies will be able to focus on product development that will set them apart from their competitors. Meeting a certain standard of product quality will also be key in standing out in a new market; measured against the growing number of high-quality cannabis products that will flow into the market, low-grade, mass-produced flower will be increasingly difficult to sell.

IV. Access to banking

If European governments succeed with the legalization of cannabis, the next area to be addressed – potentially the one that will play the largest role in the industry’s growth – should be banking. As it stands right now, cannabis companies in most US states cannot access banking services, blocking them from much needed financing and investment opportunities. Opening banking up to European cannabis companies will be paramount to seeing more businesses make their entrance on the stock market, opening them up to the kind of investment that will kickstart innovation within the European cannabis industry. Only when cannabis is legalized across the whole of Europe will investors gain the necessary confidence to accelerate the industry’s growth to its full potential.

It is important that all interested European parties, from banks and investors to long-time industry professionals, take note of the path forged by the US, as well as their missteps. Europe can use the US’ experience as a blueprint to establish a competitive medical cannabis industry – and as a lesson in how to avoid repeating their mistakes.

The Damning Consequences of a Prohibitionist's Approach to Drugs

Undoing five decades of misery caused by the UK's criminal justice approach to drug policy



By Crispin Blunt, Conservative MP for Reigate, UK, and founder of the Conservative Drug Policy Reform Group

When I was Prisons Minister between 2010 and 2012, I had my eyes opened to the scale of the UK's drug policy problem. I saw the appalling burden put on the justice system when drug users are treated as criminals, rather than people with health issues to be addressed. I realized then that, if we were to change the attitude of the establishment, we would need voices in the reasonable center to bring drug policy reform from the fringes to the mainstream.

I set up the Conservative Drug Policy Reform Group to stimulate debate on the political center-right. Our purpose is to become an authoritative voice on drug policy in the UK by sharing peer-reviewed academic contributions. Politicians and their allies in the media have been able to get away with a

sneering dismissal of reformers; now, just discrediting them as “a bunch of pot smokers” is not good enough – it is time we deal with the evidence.

As it stands, the government's drug policy is not working. Its effectiveness is contradicted by its own evidence. Consider the direct costs associated with the criminal justice implications of our prohibitionist approach alone: over half of acquisitive crime in the United Kingdom is driven by drug policy. Is that really a sign of success? We also have the highest rate of drug-related deaths in Europe. It is no wonder that countries such as Portugal and Switzerland are doing significantly better on both accounts – because their legislators have agreed on a “public health first” approach.

That is not even taking into account missed opportunities from prohibiting medical use of cannabis and psychedelics. We've got half a century's loss of research and science into the application of these drugs and their compounds that could have been making huge benefits to public health.

The reality is that politicians classified these drugs as Schedule 1 substances simply because of their reputations. Pop stars like psychedelics, so they must be bad – ergo must be banned. Worse, the basis of cannabis prohibition stems from racist sentiment towards Black Americans. There is little evidential basis for the scheduling of these drugs. (Although there are risks, as there are with all substances, they are much lower than those of other drugs.) The media have supported politicians and refused to challenge policy. Indeed, popular coverage has only perpetuated hysterical headlines that reinforce an appetite for criminal justice. We have failed to look down from our moral high mountain into the valleys and see the consequences of our policies. We have blinded ourselves to the damage they have done.

People who use drugs are considered problematic. Many are so frightened of ending up in jail that they avoid public health institutions that may be able to offer them support. By treating users as criminals, we have unintentionally produced an alliance between users and the supply chain – a business we have effectively turned into an organized crime outfit worth US\$500 billion a year. If we had a licensed and regulated drug policy, we would be able to remove the criminal element from the supply chain, making it infinitely easier to control access to these substances and protect those who choose to partake.

So how do we do that? With persistence and authority on the side of reformers. It is heartening to see that public and parliamentary opinion appears to be changing. People understand that our system is broken. Our current approach will soon become a minority position – and I am hopeful that we will see change, even if it takes a depressingly long time.

People want to use drugs. Do we really think that making drugs illegal will change millennia of human experience? Imposing decisions about substances onto those who use them will only make things worse. We need to work with the human experience, not against it, by introducing sensible regulation, licensing, and controls. We will never achieve total abstinence by the population – nor should we try to – but we can reduce the damage punitive drug policy has caused. If people can be alerted to the dangers of drugs authoritatively, they are much more likely to engage with them in a sensible way.

I don't consider myself either pro or anti-drug – I'm for intelligent policy that protects people and society. Ultimately, the only effective regulations are based on evidence – not idealism, prejudice or religious fervor – and never used as a political football.



We
BELIEVE
in
UNICORNS
(*and* **DELTA - 8**)

Contaminated product, negligent testing,
consumer safety concerns... Why is the industry
turning a blind eye to the hazards of synthetic
delta-8 THC?


*By Christopher Hudalla, President and Chief Scientific
Officer of ProVerde Laboratories, US*

Delta-8 is one of the hottest topics in the US right now. The problem: Delta-8 does not exist – at least, not in the form you might think. Everybody is arguing about unicorns. Everyone believes a unicorn should be treated humanely but the problem is that unicorns, like delta-8-THC, don't exist – certainly not in the commercial market. What do exist are heavily contaminated delta-8 products – mixtures of synthetic chemicals with impurity levels of up to 47 percent. By shifting the focus of the conversation onto the legality of delta-8, we are obscuring the real argument that it doesn't even exist yet. So how did we get here?

The 2018 Farm Bill defines hemp as “the plant species *Cannabis sativa* L. and any part of the plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or now, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.” It is easy to see the industry's thought process. CBD extracted from hemp is natural and legal. Trace levels of delta-8 have been observed in biomass; therefore, delta-8 is a natural product. And since delta-8 is naturally occurring, a derivative pathway from CBD for production is legal.


But here's the catch: The conversion of CBD to delta-8 is not a natural process. Many of the isomers and byproducts formed during the conversion are not naturally occurring, produced in the synthetic reaction to isomerize CBD to THC, which leads to both legal and consumer safety issues arising from what are essentially unknown contaminants. Synthesis is not a singular chemical reaction, but rather a system of parallel competing reactions, resulting in multiple synthetic outcomes. Many of the isomers and byproducts formed are not found in nature and have not been tested for safety or efficacy. In fact, we have no real understanding of many of these compounds. Without safety studies, and with their toxicity unknown, we cannot say they are not a health risk. As such, it would be irresponsible to recommend these products for human consumption.





I remember the first time I saw delta-10 THC gummies submitted to our laboratory. I thought: “This is cool. People are thinking outside the box. I love to see innovation.” The next thing I did was consult the literature. What do we know about the toxicity of delta-10-THC? What is the metabolic fate of the delta-10-THC molecule? Does it clear the liver? Will it cause cancer with repeated long-term exposure? Will use of these products trigger a positive drug test? Might it interact with other pharmaceutical drugs that a person may be taking? Will these compounds cause birth defects if consumed during pregnancy? What about some of the other THC isomers formed in the process? What about other synthetic byproducts? What about residual synthetic reagents left over in the product? There are lots of unanswered questions here.

Why do isomers matter?



Many people in the US have never heard of the drug thalidomide – and luckily so. US pharmacologists at the FDA turned down several requests from the distributing company because they did not provide clinical evidence to refute reports of patients developing nerve damage in their limbs after long-term use. And that prevented the drug from ever being approved for use in the US. Unfortunately, this wasn’t the case in Europe, Canada, and Australia. First marketed in 1957 in West Germany, the drug was promoted for the treatment of anxiety, sleep disorders, tension, and morning sickness in pregnant women. It took five years for researchers to realize that the drug was affecting the development of the fetus 20–37 days after conception. It is estimated that over 10,000 babies were affected by the drug worldwide. Around half died within months of being born. The thalidomide babies who survived – and their families – live with the side effects, which include issues with limbs, brain, eyesight, and hearing. Can we say with certainty that the synthetic compounds and isomers found in delta-8 products won’t do the same?

I had a client who was in ICU for 10 days after using a counterfeit THC vape product – which turned out to be a mixture of delta-8-THC with vitamin E acetate – that caused her lungs to collapse. Though it is most likely it was the vitamin E acetate that landed her in the ICU, she almost lost her life because of an unregulated product, distributed illegally. Already, National Poison Control has received around 600 exposure cases, 77 percent of which involved minors. Eighteen percent required hospitalization, with some children treated in the ICU. Are these the statistics of a safe product? And this rise in adverse events has seen key industry groups release statements. The Centers for Disease Control and Prevention (CDC) have reported that delta-8 intoxication is similar to that of delta-9,

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resulting in lethargy, slurred speech, low blood pressure, difficulty breathing, sedation, and coma. The United States Pharmacopeia (USP) said, “The prevalence of synthetically derived delta-8 THC raises safety and quality concerns related to both identity and purity – given the unknown and untested nature of the synthetic analogs and the remaining compounds.” The US Hemp Authority has also distanced itself from hemp products marketed for their intoxicating effects, including delta-8. The Hemp Industry Association has taken a different tack, advocating for safer production methods and FDA regulation of delta-8 THC, along with CBD and other hemp compounds. The FDA, on the other hand, has released a carefully worded warning letter in which they don’t explicitly say that delta-8 is a hazard, but that the products associated with delta-8 represent a hazard. And from what we see in the products submitted to our lab for testing, I agree with this position. The problem is not delta-8, but the unregulated distribution of synthetic, contaminated products.

At least Walter White
was a chemistry teacher

So, why don’t we just remove these synthetic compounds? Removal of these contaminants can be costly and time consuming, resulting in increased production costs. And that means reduced profits. In addition, the synthesis uses toxic chemicals and organic solvents. The resulting mixtures, in addition to non-natural isomers and synthetic byproducts, can contain residuals of these toxic reagents.



Most producers are not testing for acids, residual solvents, neutralizing bases, and heavy metals. How adept are producers at removing these residual reagents from their process? Without more testing, we'll never know. And that brings us to another problem: The DEA has said multiple times that synthetic cannabinoids are illegal – but who is willing to say delta-8 is synthetic? Not politicians, lawyers, or regulators, who are focused on the legality of delta-8. Not law enforcement who are afraid to enforce sanctions, arrest people or confiscate products. To make matters worse, much of the product is found via the internet, in which the producer may be nebulous – and difficult to hold accountable. All this ambiguity has created a huge window of opportunity for producers – and, of course, delta-8 has become a money printing machine, which nobody wants to disrupt. But given that many of the isomers formed do not exist naturally, they can only be classified as synthetic.

Another issue: Producers are oftentimes unaware that they are distributing crude mixtures of synthetic contaminants. Right now, most laboratories providing cannabinoid testing for these producers are using HPLC as their primary methodology. But these methods were optimized for cannabinoids found in the cannabis plant, and as such, are incapable of resolving many of the synthetic cannabinoids and synthetic byproducts. It's like using a screwdriver to pound a nail; though I love screwdrivers, it's just not the right tool for the job. And so there are often multiple chromatographic peaks hiding behind the delta-8 signal. Recorded retention times of these peaks do not match exact cannabinoid reference standards, so their presence is often omitted from laboratory reports.

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Without chromatographic resolution of these chemical compounds, these contaminants are often integrated into the delta-8 signal. Consequently, products that claim to be 90 percent delta-8 typically contain contaminants that have been erroneously attributed to the delta-8 signal. Many of the cannabinoids have similar retention and UV absorbance, making it difficult to distinguish individual isomers. The similarity of these structures is part of the reason why they are so challenging to resolve in a singular chromatographic method. The use of orthogonal analytical methodologies, such as gas chromatography or supercritical fluid chromatography, can be used to separate some of the chemical contaminant signals from the delta-8 signal, but this takes extra time and extra resources.

There are no two ways about it, 100 percent of delta-8 products that have been tested by our lab are heavily contaminated with synthetic byproducts. Most labs are not telling producers that they have found synthetic isomers and/or contaminants whose signals cannot be resolved from delta-8. With labs not reporting what they are seeing, producers are being led to believe that they have high quality delta-8 distillate. Naturally, they go on to make that distillate into vapes, edibles, and so on, and carry those contaminants along in the process.

Why do so many labs ignore the presence of these compounds? Are they just not able to understand what the chromatography is telling them? Are they afraid of losing the testing business from these producers? Our lab has lost significant testing revenues based on our policy for delta-8 samples, which includes noting the presence of these contaminants on our Certificate of Analysis (COAs). Nobody wants to send me a second vape cartridge for analysis when my first report came with a warning: No toxicity data is available for these unknown compounds, and as such would not be recommended for human consumption.

Although labs are part of the problem, they are not the only guilty party. Producers can plead ignorance because labs have not been forthcoming with the truth – or incompetent with their testing. But when I show producers what is really in their sample, they don't stop making it, they don't stop distributing it – they just go to another lab who will not acknowledge the contaminants found. Few other labs in the US will call attention to contaminants in the products we test, providing a clear warning that a product may not be safe or recommended for human consumption. And when consumers are provided with test results to confirm safety, at least against agricultural contaminants of concern, they are misled by the omission of data indicating contaminants that would be of a synthetic nature and

“THE SCIENTIFIC COMMUNITY, FOR THE MOST PART, HAS BEEN VERY SUPPORTIVE VERBALLY – BUT FEW PEOPLE ARE STEPPING UP TO TAKE A PUBLIC STANCE AGAINST SYNTHETIC DELTA-8.”





therefore of concern. In reality, we cannot say these contaminants are harmful for human consumption, but – more importantly to me – I also cannot say they are safe. The scientific community, for the most part, has been very supportive of our stance on consumer safety – but few people are stepping up to take a public stance against synthetic delta-8 products and the associated contaminants.

The solution

So, what do we do about it? The answer is to look to industries dedicated to manufacturing and testing synthetic compounds for human consumption. How is Viagra manufactured? Trained people put chemicals together, perform several synthetic reaction steps, and finally get to the desired compound – but never with 100 percent yield. And that could mean a multitude of synthetic reaction byproducts. Those unintended synthetic compounds are treated one of two ways: i) They are either removed through a purification step – like chromatographic isolation, or ii) these compounds are studied to ensure they are safe for consumption, to ensure their presence in a final drug product will not cause harm. Nobody that I know of is doing that for delta-8.

“ WE HAVE BEEN WORKING COLLABORATIVELY WITH MULTIPLE EQUIPMENT MANUFACTURES THAT PROVIDE INSTRUMENTATION CAPABLE OF THE NECESSARY ISOLATION OR PURIFICATION OF CHEMICAL COMPOUNDS, LIKE DELTA - 8 . ”

In fact, we haven't even identified many of the resulting compounds from delta-8 synthesis. Each producer or each batch that uses different acids, different temperatures, or different reaction times creates a different mixture of contaminants – so contamination profiles in these products can differ greatly. But we do see some common foreign signals in many of the products, and with the application of multiple analytical techniques, we are starting to get bits and pieces of information. In one sample, the mass spec isotopic ratios observed are indicative of a chlorinated molecule, with the mass of hexahydrocannabinol. We don't have the complete picture, but chlorinated cannabinoids are probably not a good thing. Recently, researchers have published studies using nuclear magnetic resonance spectroscopy, along with chromatography and mass spectroscopy, to identify some of the structures they found in selected consumer products. Several of the structures found, including one compound that has not been previously identified, have not yet been studied for safety or toxicity.

We have been working collaboratively with multiple equipment manufactures that provide instrumentation capable of the necessary isolation or purification of chemical compounds, like delta-8. These collaborations demonstrate that there is hope for legitimate delta-8 products. I have presented much of our data and concerns at conferences, and while much of the data is not favorable for delta-8 product lines, I like to end my presentation with examples from these collaborations of what delta-8 could look like. That is, what delta-8 should look like. And yet, I'm left somewhat amazed after my presentations. I present an alternative to the current contaminant-produced products, but do not get asked for additional follow up information on the conditions, equipment or collaborators which were capable of producing a purified product. It seems that most producers just are not interested because of the additional resources necessary to pursue this alternate route.

And make no mistake, it will take time to gain clarity on these compounds. They all need to be purified, isolated, and characterized. If they cannot be removed by purification, then they need to be studied for biological safety. Unfortunately, my lab doesn't have the equipment to purify and study all these contaminants. But even for researchers that have access to this equipment, it will take years to get the full picture and understand these complex mixtures completely. With the unregulated, non-standardized industry, the contaminating compounds are part of a shifting landscape; as noted, every time we see variation in the process, there are subtle (or major!) differences in resulting contaminant profile. And as long as people continue to change their processes, there will be new contaminants and new risks. No wonder it takes millions of dollars to bring a regulated drug to market...

Self-regulate or die

I want the industry to self-regulate so outside organizations don't have to shut it down. But I don't see that happening... Many in the industry instead are trying to move regulation of delta-8 under the US Farm Bill so it is treated and regulated like hemp. But this delta-8 is not an agricultural product. I am frustrated when producers present a COA which includes pesticide screening results. Pesticides are contaminants of agricultural concern. As soon as the added acid starts changing the chemical structure of CBD, it leaves the world of agriculture and enters the realm of synthetic chemistry – but farmers are not synthetic chemists. And neither are cultivators, extractors, nor most processors. If delta-8 should be regulated, it should be overseen by the same organizations that regulate other synthetic chemistry products intended for consumption: In the US, most likely the FDA. But FDA regulation of CBD, and with it, delta-8, would be challenging because it would mean producers would have to follow legitimate processes to produce their goods. These processes, which would include GMP production, are neither easy nor inexpensive to implement and maintain. FDA-regulation means audits, paperwork, manufacturing practice guidelines, as well as safety and stability studies. The bureaucracy associated with an FDA-regulated program would crush most current CBD and delta-8 producers, inevitably forcing consumers to the black market. But without any regulatory oversight, many states have already started to shut delta-8 products down. At the last count, 17 US states had outlawed delta-8 products – with no oversight, no responsibility, and no integrity – driving producers and consumers underground. And that's especially disappointing because delta-8 (without the contaminants) has legitimate therapeutic potential.

The silver lining

Raphael Mechoulam was one of the first researchers to see the therapeutic potential of delta-8. It has significant neuroprotective properties. It is also an appetite stimulant – and it has analgesic properties in terms of neuropathic and inflammatory pain, as well as anxiolytic properties, binding to CB1 and potentially CB2 receptors. Its antiemetic effects have been studied with pediatric chemotherapeutic treatment in the reduction of nausea to great success. In fact, delta-8 has an almost identical therapeutic profile to

“THE BUREAUCRACY ASSOCIATED WITH AN FDA-REGULATED PROGRAM WOULD CRUSH MOST CURRENT CBD AND DELTA-8 PRODUCERS, INEVITABLY FORCING CONSUMERS TO THE BLACK MARKET.”





waiting for FDA approval of CBD. These are all incredible benefits, but they must be treated with caution.

It worries me that the synthetic version of delta-8 has become so palatable to the cannabis industry. So much so that the industry is now comfortable moving forward with additional chemical modifications.

In the last few months, we have seen hexahydrocannabinol (HHC), THCP, delta-8 THC acetate, and delta-9 THC acetate (THCO) – synthetic cannabinoids

that aren't even pretending to be phytocannabinoids. And yet these are

being sold as legal hemp derivatives, "Farm Bill compliant," which, according to lawyers, is lawful.

To put that into context, if you could find a synthetic pathway to convert CBD into methamphetamine or heroin, that synthetic process would make those products legal – after all, it would still be a hemp derivative. Really?

As long as I feel that consumers need to be warned about the risks associated with delta-8 products, and as long as regulators and health care professionals need to understand what these are, I will continue to be a mouthpiece for unpopular opinions. I cannot deny that I am also driven by scientific curiosity; it is very frustrating to say that I've found compounds or chemical signals that I cannot identify, and include that note on our certificate of analysis. But the laboratories who are not prepared to acknowledge these unknown compounds are doing no benefits to producers and consumers.

We certainly have the means to produce a clean, uncontaminated delta-8 with proper post-synthesis isolation and purification. It will take time, money, research, and regulation, but it will be worth it. I just need more people – preferably the whole industry – to see the light.

In the meantime, I still want to believe, so I will keep watching for legitimate delta-8 (and unicorns).

delta-9, but with only 20 percent of the psychoactivity.

If prepared without contaminants and used correctly, it could allow healthcare providers to treat the most vulnerable with cannabinoids, without getting them high.

From a commercial perspective, delta-8 is relatively easy to produce from CBD (at least without regulatory oversight) –

and that's currently in overabundance. It requires minimal capital investment for production equipment and supplies, making it incredibly attractive to suppliers – especially in our turbulent economy. With the exception of purification, delta-8 can be produced inexpensively. So once we find a way to scale the purification process, those costs will also be reduced. And because the oversupply of CBD isolate has resulted in lower margins for manufacturers, conversion to THC represents a significant financial opportunity and provides salvation for investors

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From Basketball to Biology – and Beyond

Sitting Down With... Annabelle Manalo Morgan,
Professor in Cell and Developmental Biology
and Visiting Scientist at Vanderbilt University,
New Orleans, Louisiana, USA;
and Founder of Masaya Medical



What did you want to be growing up? The female Michael Jordan – and I still do deep down. I never wanted to be a doctor or scientist, I just wanted to play basketball. I grew up in a small farm town in Saskatchewan – one of the coldest places in Canada. It can get down to -50 °C, so it's no coincidence I chose a sport where I could play indoors. I didn't just love the sport – I loved the drive and competitiveness I saw in those players. I told my mom and dad, "I'm going to play basketball." My parents, traditional Filipinos, said I should be a nurse or a doctor. I got an academic scholarship to Toronto to play ball, but majored in biology to keep them happy. It was there I was scouted and came to the United States. I was playing collegiate basketball in New Orleans when Hurricane Katrina hit. It was devastating. President Bush gave a list of alternative universities that flood refugees could attend. I ended up at a school in eastern Kentucky, took a double major in biology and chemistry, and never picked up a basketball again.

How did you get into cannabis? First and foremost, I'm a molecular and cell biologist. I spent over 10 years at Vanderbilt University working in neuroscience and cardio-oncology before I moved into the clinical trial space. Cannabis never crossed my mind until my son (and third child), Macario, was born with epilepsy. It was so severe that he had 40 percent of his brain removed at five weeks old and was put on every medication going. As a scientist, I trust protocols – but I could see that those medications weren't enough. My son wasn't developing. I started questioning whether they were healing his brain or just covering a bigger problem. I'd never had to deal with patients before, so I'd never questioned the functional side of medicine. I started looking at peer-reviewed research on epilepsy and cannabinoids came up again and again.

I decided to formulate my own medicine for Macario – a CBD base that had a high absorption rate. I asked my colleagues at the time to test it for stability without telling them what it was. They told me it was safe. I took my son off all of his medications and started giving him this formula. Within two months, he came to life. He laughed for the first time a week later. Imagine being six months old and never having laughed. Two months after that, he was crawling. Because he's missing almost the entire left side of his brain, he's supposed to be paralyzed on the right side of his body – but there he was crawling left, right, left, right, just like my other kids. At 14 months, he was walking.

At that point, I could have walked away with my healthy son and continued to work in my lab – but I felt that I needed to give other families the same opportunity we'd had. That's when I decided to give my life to cannabis.

Could you tell us more about the study you're working on now?

I knew I could never stand in front of the NHS or FDA and tell my story or any of the million others and expect them to approve a drug. They are nonbelievers. What they want is data – so I said, "Let's give it to them." I came up with the concept of a fibromyalgia and chronic pain study that fast-tracks traditional timelines by running phase trials in parallel – in vitro, in vivo, pilot in human, safety, and efficacy all at once. The human pilot study, which looks at three CBD tincture formulas, will start in the UK in coordination with an internationally recognized clinical research group based at the University of Manchester; parallel molecular and pharmacokinetic studies will be conducted in the US. I met with Flora Medical by chance and told them about what we were hoping to do and that nobody would fund our study. They understood our goals and decided to get involved – and I'm so grateful for their support.

*"I learnt that,
if I worked hard
with good intent,
things would come
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but one way
or another."*

Why fibromyalgia?

Two reasons: one, there are still no true markers for it, and two, the symptoms are seen in a lot of other conditions – pain, inflammation, anxiety, depression. It allows us to take a wide-angle view, but funnel in when we need to. We don't want to limit the study – we want to learn as we go along – but, ultimately, we want to know the true synergistic benefit of isolated CBD and be able to define it not only in patients, but in the lab – literally cells in a dish. Usually, the FDA or NHS need to see this data before you even approach a patient, so we're having to convince them that cannabis is so safe that what would typically take 20 years can be done in five.

Do you imagine there will be pushback to doing trials this way? It's going to be a fight. That's why it was so important to get the right people involved – people who normally wouldn't even look at cannabis. But the way we do

science needs to change. What happened with my son made me realize that I spent seven years in a penthouse lab at the top floor of the cancer center and I never knew the name of one treating physician or oncologist. There's a disconnect between science and medicine – and cannabis is a great platform to bridge that gap.

Why did you pursue a career in academia? I've always had a hierarchical understanding of life. I know that if you want to make change, especially as a woman of color, you have to get to the top of the ladder to create the credibility that allows you to have these conversations without judgment. It doesn't matter who the other person is, because we went through the same schooling and can stand toe-to-toe. I did what I had to do to get a seat at the table.

What are your long-term goals? Not to sound like a superhero, but I want to change the face of medicine – specifically, the protocol-based approach we have today. I would love to see translational medicine used in practice, with people from different scientific backgrounds working together to evaluate patients in a number of different ways to provide the best possible personalized care.

Why don't we take this approach already? Money drives the way things are. I have been involved in studies where funding stops at the molecular level, which makes no sense – that's the meat that would go on to create a medicine that could then be used in a clinical trial. Our current system is so tightly controlled that scientists do the work, only for it to be either shelved or published in a paper – and that's it. Departments are put into boxes (driven by the people willing to fund them) and the gaps between them are never bridged.

Why is there such a disconnect between specialties?

It's difficult for scientists to speak translationally about what we do – it's a whole different language. We need to get better at communication because, if we can't get doctors to understand what we're talking about, how are they going to explain it to their patients? Education must be at the forefront of our work because, ultimately, knowledge is power.

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that gap.”*

How did you find shifting from basic science to cannabis?

In basic science, you create hypotheses based on existing work. In cannabis, you create hypotheses based on hints and clues (because so little information is available), which is incredibly exciting. I believe our work will take cannabis to the next level and help us better understand the plant as a whole. It will allow us to sit in front of legislators and prove that cannabis really is no different than any other compound. We know it's great; we know it's safe; we just need the data to prove it.

How do you stay motivated?

I'm very strong-willed. I've been through

a lot at 38 years old, but I've prevailed, and so I feel it is my duty to be an example to other women – to other moms, scientists, and leaders. I make no excuses. I think that comes from my basketball days when I was very young and very hungry. I learnt that, if I worked hard with good intent, things would come around in the end – maybe not necessarily in the way I wanted, but one way or another.

You touched on the difficulties of being a single mother working in these spaces.

What needs to change to encourage more diversity in industry and academia?

For real change to happen, there has to be movement from both sides. We need to open our doors to people who might not have the perfect resume. And, as a candidate, you have to develop the right mentality to sit at that table. You've got to stand up to the challenge. Getting the role is one thing, but being able to sustain it – to be powerful and to understand that you're representing a whole flock of young women – is another. In my mind, women are natural leaders, so I love to see the confidence of the women who are taking those roles. But those doors have to be opened first. And, once they are, we need to step through them with power.

Outside work, what makes you happy?

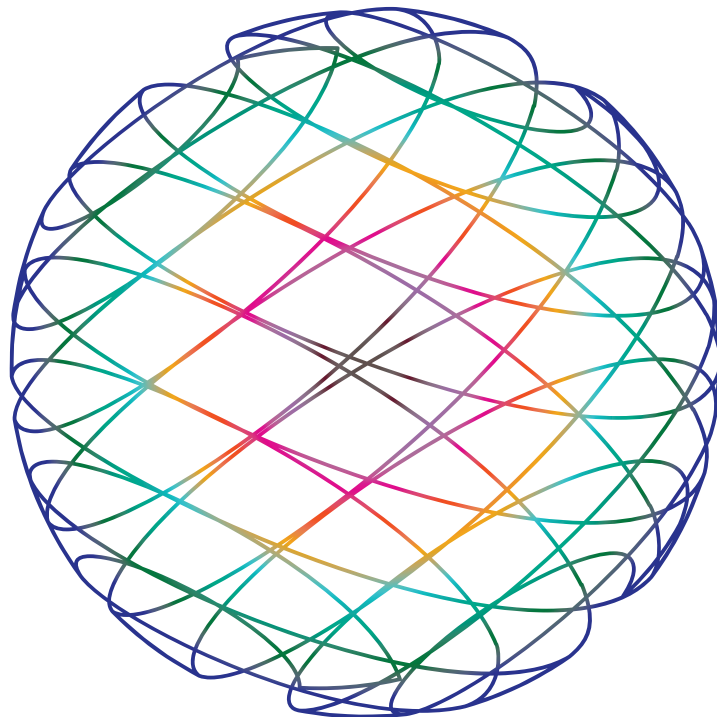
Nothing makes me happier than seeing my family happy.

Who is your biggest inspiration?

My mom. I watched her work her tail off, never complaining and never giving up. I am who I am today because of her.

Any advice to your younger self?

Never forget who you are and where your intentions lie. You lose sight of that sometimes. Always have a goal in mind. Work out what you want to achieve. Does this decision – whatever it might be – contribute to your long-term vision or will it distract you?



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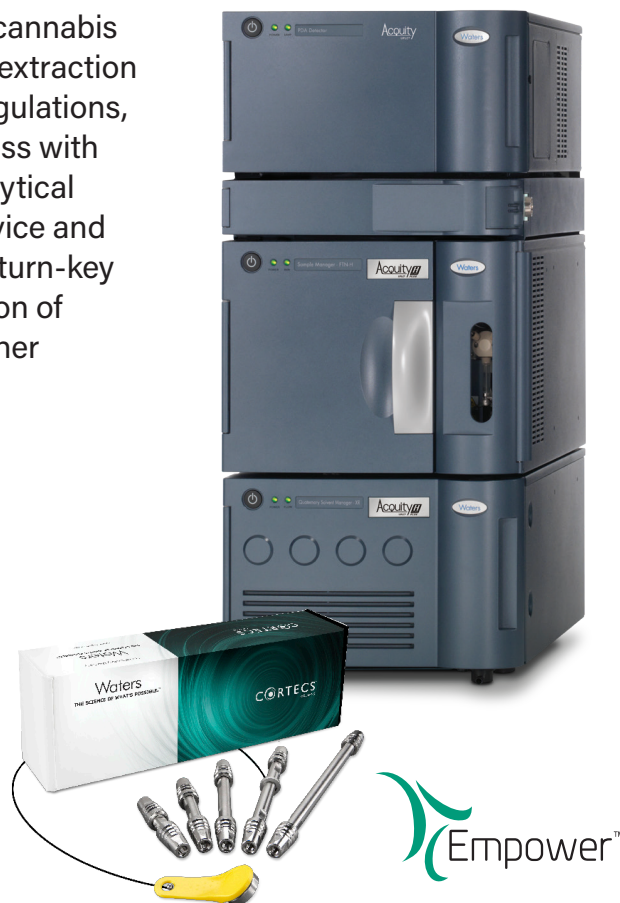


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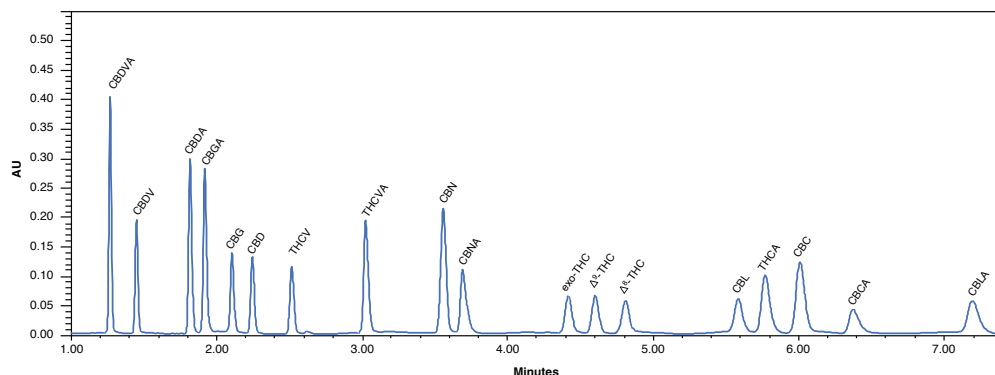
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