

^{the} Cannabis Scientist

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E ditorial The importance of changing your mind	Upfront COVID-19: how is the industry coping?	In My View Why scientists should be CEOs	Sitting Down With Cannabinoid guru, Roger Pertwee
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How to Change Your Mind

In these uncertain times, the last thing we need is certainty





rogress is impossible without change, and those who cannot change their minds cannot change anything." – George Bernard Shaw

Many of us shake our heads at a political climate that has become so polarized that even a global pandemic is an opportunity for point-scoring. "We're scientists," we say. "We want facts and figures, not propaganda or doom-mongering."

But science (and cannabis science in particular) can be partisan too; studies exploring adverse effects and medicinal uses alike are often filtered through the political lens of legalization versus criminalization.

Humans are programmed to form "tribes" – and the more adversity or opposition they face, the stronger their allegiance. With years of prohibition followed by a dramatic swing to legalization, it's no wonder that an "us and them" mentality has evolved around cannabis. The key? To recognize your bias and consciously seek out opposing evidence (or, at least, don't reject it out of hand) – something that is easier said than done, of course.

To help navigate the sometimes choppy waters of cannabis science, we recently launched a new weekly newsletter: The Cannabis + Cannabinoid Curator (C+CC). As Editor of The Cannabis Scientist, I spend a lot of time exploring the latest research and trends in cannabis testing, processing, R&D, and regulation. In The C+CC, I share the cream of the crop with an audience of scientists, executives, and anyone else who wants to stay up to date with the latest science in the space – whether that's a promising medical application or a concerning side effect. To subscribe, visit www.texerenewsletters.com/cccsubscribe.

Changing our minds (without changing our core values) is a skill we are likely to need a great deal of in the weeks and months to come. A case in point: I have repeatedly (and somewhat wearily) stated over the past few weeks: "No, I don't believe vaping cannabis/taking CBD oil/gargling warm water will fight off COVID-19." And I will always stand by my belief that it is wrong for companies or individuals to take advantage of people's terror by promoting unproven therapies (a view shared by the FDA). But it appears that research at several universities is examining the use of cannabis constituents as antivirals against SARS-CoV-2. If they ultimately prove effective in clinical trials? I will be positively delighted to change my mind about whether cannabis can cure COVID-19 after all!

Charlotte Barker Editor

Cherle Kerler

WEEKLY NEWSLETTERS

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The week in cannabis science

COVID-19 Curator

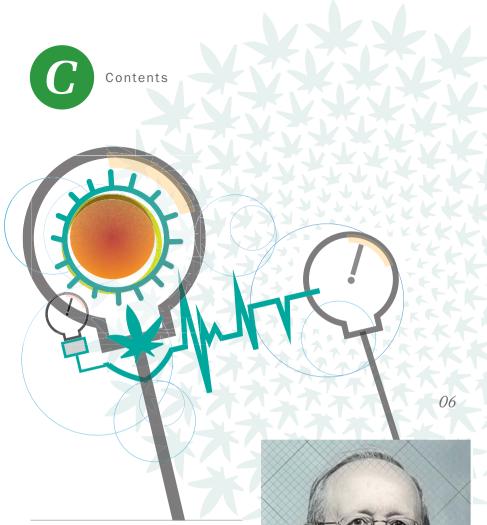
The emerging science of the outbreak

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03 Editorial How to Change Your Mind, by Charlotte Barker

Upfront

06 The latest news, views, and research – from COVID-19 to the cost of testing

In My View

- 10 Alisia Ratliff has a question: Why don't cannabis companies hire scientists as CEOs?
- 11 Better milling could boost extraction efficiency and save money, according to Sajni Shah and Markus Roggen



Feature

12 California Dreamin' Three Emerald Conference speakers share their hopes (and fears) for the industry

Sitting Down With

26 **Roger Pertwee**, Emeritus Professor, University of Aberdeen, UK

Cannabis Scientist

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Pandemic Pressure Points

How is COVID-19 affecting the cannabis industry?

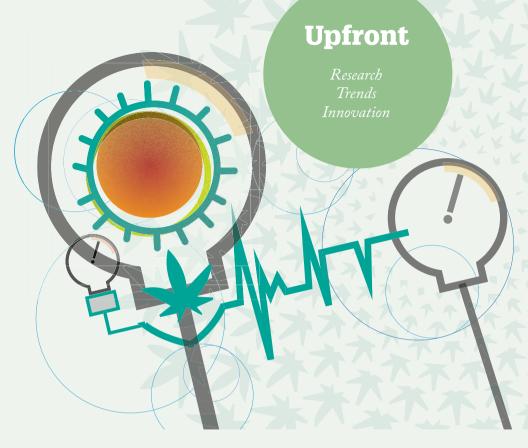
The good...

Cannabis dispensaries in many territories are being classified as "essential businesses," alongside pharmacies and food shops – a move welcomed by industry associations and patient groups.

Meanwhile, cannabis companies are rallying to join the fight against the virus. A number of cannabis extraction labs are leveraging existing ethanol supply chains to produce much-needed hand sanitizer at high volume, some of which is being donated to police, firefighters, and healthcare staff. Regulated cannabis labs in Canada have even been approached by the government about carrying out COVID-19 testing.

The bad...

The economic implications of the pandemic will be looming large in the minds of cannabis companies and investors after a tough year for the industry. US companies' problems may be compounded by the fact that they are excluded from government financial aid due to the illegal status of the drug at a



federal level.

Many conferences are being postponed or canceled, including CannaTech Tel Aviv and Cannabis Science Conference East.

And the ugly...

The FDA has issued warning letters to several CBD companies for making false health claims about COVID-19. The agency encourages reporting false claims via an online form at

https://bit.ly/2YaG0R3.

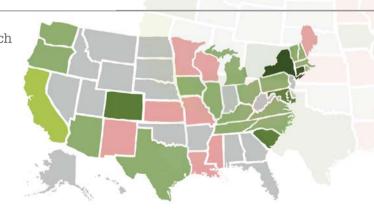
The International Association for Cannabinoid Medicines board said in a statement, "Several laboratory studies suggest that cannabinoids may have antiviral and antibacterial effects [...] However, there is no evidence that individual cannabinoids – such as CBD, CBG, or THC – or cannabis preparations protect against infection with the SARS-CoV-2 virus or could be used to treat COVID-19."

INFOGRAPHIC

Research Rankings

Which US states have the largest number of active cannabis clinical trials on clinicaltrials.gov? Cannabis research by state

40 - 50 studies 30 - 39 studies 20 - 29 studies 2 - 19 studies 1 study 0 studies





POLICY PRÉCIS

We catch up with the latest twists and turns in cannabis regulation

- Prescription progress. For the first time, a cannabinoid medicine (Epidiolex, a CBD-based therapy used to treat Dravet syndrome) has been descheduled by the US DEA.
- Better cannabis, better research. After a four-year delay, the US DEA has announced it will review 37 applications to grow cannabis for research, and published a draft framework for growers.
- What is a "unit" of THC? The NIDA has issued a request for information from researchers to help establish a standard dose of THC (they are proposing 5 mg), which they believe will allow a more systematic study of the benefits and harms of cannabis use.

- Registration reprieve. Following criticism, the USDA delayed the requirement for all hemp testing to be carried out at DEA-registered labs until October 2021, or publication of the final rule, whichever comes first.
- Hurry up and wait. A UN vote on rescheduling cannabis products was... rescheduled. The vote was due to take place in March at the 63rd session of the United Nations' (UN) Commission on Narcotics and Drugs (CND) in Vienna. It will now be held in December.
- Lebanon legalizes. Cannabis cultivation is now legal in the Middle Eastern state – but crops must have THC levels below 1 percent.

For links to the original announcements, visit the online version of this article at tcs.txp.to/PolicyMay20



I Smell a High

Lab rats seek out vaporized THC

Researchers have struggled to replicate human patterns of recreational cannabis use in laboratory rodents – when it comes to cannabis, rats tend to "just say no," showing little interest in selfadministering the drug. But a recently published paper suggests that delivering cannabis as an inhaled vapor could make a difference. The study authors trained rats to put their noses into a tube in their cage to administer puffs of cannabis or air.

Rats that were given the option to selfadminister puffs of vaporized THC-rich cannabis showed more drug-seeking behavior compared with rats who received puffs of CBD-rich cannabis or plain air.

The authors hope the model will be

a useful proxy to understand more about recreational cannabis use in humans, concluding, "This approach will be valuable for interrogating effects of cannabis and delineating neural mechanisms that give rise to aberrant cannabisseeking behavior."

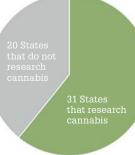
Reference

 TG Freels et al., J Neurosci, 40, 1897 (2020). DOI: 10.1523/ JNEUROSCI.2416-19.2020

States with no active cannabis trials

Alaska, Arkansas, Hawaii, Florida, Nevada, Utah, Idaho, Montana, Wyoming, North Dakaota, South Dakota, Nebraska, Oklahoma, Indiana, West Virginia, D.C, Delaware, New Jersey, Georgia, Alabama

Source: ClinicalTrials.gov data compiled by Growcola. See more at https://bit.ly/3aDRqPD.



Top 3 states for cannabis research

- 1. Connecticut 43 studies
- 2. New York 42 studies
- 3. California



Chain Reaction

Exposure to a potent cannabinoid makes adolescent rats more sensitive to cocaine

A study found that prolonged exposure to high doses of synthetic cannabinoid WIN 55,212-2 (WIN) in adolescent rats changes how their brain reacts to later cocaine exposure. The research has generated some heated headlines, but does the study really prove that "cannabis is a gateway drug," as The Daily Mail claims? To find out more, we spoke to co-author Philippe Melas.

What prompted the research?

Existing epidemiological and preclinical evidence led us to a hypothesis: cannabis exposure during critical neurodevelopmental periods (e.g., in utero or in adolescence) can reprogram the brain to increase susceptibility to neuropsychiatric disorders, including substance abuse. To our knowledge, our study is the first to map the molecular and epigenetic changes that occur when cocaine interacts with adolescent brains already exposed to cannabinoids.



What were the key findings?

To our surprise, we found that exposure to cocaine caused a number of unique molecular changes in brains already exposed to WIN, compared to brains that had not been exposed to cannabinoids. Even more interesting was the fact that both behavioral and molecular changes were confined to adolescent animals only, and not adults.

Why use WIN for this study, rather than THC?

Animal studies have shown that plant cannabinoids (such as THC) and synthetic analogs (such as WIN or CP-55,940) result in similar neurochemical changes in the brain. However, rodents do not readily self-administer THC. We opted to work with WIN initially so that we could complement our studies with selfadministration procedures. However, we plan to use THC in future experiments to verify the molecular and epigenetic changes we reported in this study.

What's next?

We want to discover whether our molecular findings in rats translate into humans. To do so, we have partnered with the NIH NeuroBiobank to study postmortem brain samples from people who had been dependent on substances such as cannabis and cocaine.

Reference

 M Sherma et al, Proc Natl Acad Sci USA [Epub ahead of print] (2020). DOI:10.1073/ pnas.1920866117

Gut Feeling

IBD patients use cannabis to control symptoms

One in five Australians with inflammatory bowel disease (IBD, which includes Crohn's disease and ulcerative colitis) are using cannabis to treat the condition, according to a survey by the Lambert Initiative for Cannabinoid Therapeutics at the University of Sydney. The vast majority of the 853 respondents who used cannabis obtained the drug illegally, with only three people reporting access to legal cannabis.

Of patients using cannabis, 93 percent reported that it is effective in treating their symptoms, including pain, difficulty sleeping, and anxiety. However, cannabis users reported side effects of memory impairment, fatigue, and drowsiness, were less likely to engage with specialists, and suffered

more hospitalizations than non-users. While the survey cannot say whether cannabis is effective in managing IBD, the authors hope that it will trigger more clinical trials in this space.

Reference

1. MJ Benson et al., Crohn's & Colitis, 360, 2, otaa015 (2020). DOI: 10.1093/crocol/otaa015



Reasons to Bee Happy

Hemp crops make for diverse bee communities, according to a new study. Entomologists from Cornell University found that industrial hemp farms supported 16 different species of bees, and suggest that hemp could provide a valuable source of food for bees at a time

of year when few other plants are flowering. Reference: NR Flicker et al., Environ Entomol, nvz141 (2019). DOI: 10.1093/ee/nvz141. Credit: Heather Lee Grab.

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$\ensuremath{\textbf{QUOTE}}$ of the month

"I task anyone embarking upon a new venture in the cannabis field to appoint a CEO with a scientific background, break out of the rut that cannabis startup companies are currently operating in, and see where that momentous decision takes your new venture."

Alisia Ratliff explains why scientists should be CEOs on page 10.

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Why Scientists Should be CEOs

Too many cannabis start-ups are stuck in a rut – to truly innovate, we need technical expertise at the top

By Alisia Ratliff, CEO, Victus Capital Ventures, Jacksonville, Florida, USA.

"The definition of insanity is doing the same thing over and over again and expecting a different result" – Albert Einstein.

By the above definition, it might be considered that insanity is not placing a scientist at the highest-ranking office of your vertical cannabis company. Currently, many CEOs of cannabis startups were awarded the position (with varying degrees of nepotism) by early-stage investors and tasked primarily with updating the board of directors on the progress of the company. Given that a decent enterprise resource planning system can do that job, it's no surprise that this business strategy has proven to be uninspired, inappropriate, and paralyzing to new companies in a competitive industry.

Over and over, we've seen investors employ chief level officers who can only manage a copycat business model. With limited understanding of the technical aspects of the business, these executives hire visionary scientists to build, develop and run all aspects of the operation – but once the company is up and running, there's a change of heart. The business is growing, costs must be cut, revenues increased – and who needs scientists for that? Soon the scientists are purged from the organization and the executives are running the show.

Unfortunately for them, the instruments that support the industry aren't exactly blenders and toasters. If the scientists working in analytical, extraction and R&D aren't led by other scientists with more experience and vision, where will the company go? Probably



in the same direction as every other cannabis company out there right now. I believe there must be more noble goals in the cannabis industry than making money and protecting the interest of your investors. Besides, are you really protecting your investment by doing the same thing as everyone else?

If a CEO has the job of managing a company's resources, spearheading growth initiatives and driving the company's success in a scientific endeavor, it seems desirable that they should have some laboratory experience under their belt. I hear the term "leverage" frequently used by non-scientist chief-level agents. If the head of a firm spends all day leveraging scientists to get the job done, then what exactly is the job they're performing?

Blind spots are defined as subjects in which one is uninformed, prejudiced, or unappreciative. A specific type of blind spot that is prevalent among most executive leaders is the "theory of incongruency," which holds that our expectations cloud our perception. The theory suggests that many ground-breaking ideas are ignored because leadership is unable to see the value of a new idea that doesn't fit within their current expectations and company culture (1).

So why aren't companies considering scientists to head up their operations? I believe the root of the issue is fear – on both sides of the equation. For a company investor, it may feel safer to hire someone known to you, with a similar background to your own, rather than a scientist – often stereotyped as having a narrow focus and lacking business acumen. From the scientist's perspective, some may fear rejection for high-level roles, or feel uncomfortable venturing outside the lab. I won't deny we scientists have a love for the craft at the bench level. But this passion does not exclude the many other attributes, knowledge, and leadership we bring to the table.

I have personally confronted many scientific dilemmas that required an extensive practice in critical thinking and analysis. As a project manager, I am trained to connect different elements of business while actively forming conclusions. Running a vertically integrated cannabis company is like aiming to hit a moving target. There are so many factors that directly and indirectly affect one another; company-wide collaboration is imperative. However, once there are several solutions on the table, it is the responsibility of the CEO to make the best, most-informed decision moving forward. How can the leader of an entire organization make qualified, data-driven decisions without having the foundational knowledge necessary?

A scientist leading a cannabis company is not a gallant gesture, but an essential action to conceptualize, develop and grow a technical organization. Only a scientist will know how to qualify thirdparty laboratories and validate their analytical methods or identify safety issues in plant material that could cause a major downstream impact to production. Laboratory experience also adds value when it comes to choosing equipment and identifying relationships to be created and nurtured amongst your stakeholders.

Scientists are not only vital to the processes

being performed across the organization; they are the people who are capable, qualified and poised to lead a sustainable cannabis company. I task anyone embarking upon a new venture in the cannabis field to appoint a CEO with a scientific background, break out of the rut that cannabis startup companies are currently operating in, and see where that momentous decision takes your new venture. In my view, you

certainly won't be disappointed.

Reference

 JM Kerr, "Business blind spots" (2014). Available at: https://bit.ly/38Tdx41

Size Does Matter

Why use milling prior to cannabis analysis or extraction?



By Sajni Shah, Research Associate and Operations Assistant and Markus Roggen, Founder and CEO, Complex Biotech Discovery Ventures, Vancouver, Canada.

With the emergence of numerous cannabis extraction companies (1) and the declining prices in a maturing industry (2), extraction efficiency has become increasingly sought after. Unfortunately, current cannabis extraction methods have been scaled up from home-grown methods, and thus may not be optimized for industrial scale.

One aspect of extraction we found intriguing to study early on was the particle size of cannabis flower, and what effect it might have on the extraction of cannabinoids and terpenes. Someone once asked, "If you grind the cannabis flower, does it break the THC molecules?" Contrary to his belief, we cannot cut molecules apart, but we did wonder whether milling would lead to the degradation of cannabinoids and terpenes. In particular, the heat generated from milling was of concern – would it cause the conversion of THC acid to THC? To find out, we compared non-ground plant material to different grind sizes, ranging from 0.5 mm to 10 mm. We found no significant difference between the concentration of cannabinoids and terpenes across different particle sizes. In addition, the ratio of THC acid to THC was not affected.

Now we know that the cannabis flower is not degraded by the process of grinding. Then why do we bother incorporating this extra step in our extraction process? Our research found that smaller particle sizes led to higher recoveries of cannabinoids and terpenes, as well as better extraction selectivity.

Using supercritical carbon dioxide as a solvent, we extracted the cannabis plant material at different particle sizes ranging from 2 mm to 10 mm and compared the results to non-ground material. We found that the smallest particle size, 2 mm, had the highest recovery of cannabinoids and terpenes. We then focused on two different extraction conditions, first for the selective extraction of terpenes, the second for cannabinoid extraction. Under the first set of parameters, we were looking for a high concentration of terpenes and a low concentration of cannabinoids. For these conditions, cannabis cut with a food processor showed the best results. And the 2 mm particle size was a close second. For the second set of parameters, 2 mm was the highest yielding and had the highest concentration of cannabinoids and the lowest concentration of terpenes. This shows that, depending on the parameters chosen, you can gain a high concentration of the target compounds, and the smaller particle size helps ensure that the extract remains at high purity.

You might be thinking "Okay, great, but is it really worth adding the extra grinding

step?" Let's discuss this in a language most will understand – money. Take the hypothetical scenario where a company has run 60 extraction runs in total over the span of a month at two runs per day. An average 20 L extractor can hold 3 kg of un-milled plant material, but at the 2 mm particle size, it can hold 4.5 kg of plant material due to the higher packing density. Assuming all other factors remain the same, that is an additional 1.5 kg of plant material extracted per run – an extra 90 kg over 60 runs.

If we assume a value of \$10 per gram of extract, at an 18 percent yield, that equates to an additional \$162,000 of extract produced in that month. Suddenly, the topic of grinding cannabis plant material seems much more exciting!

Ultimately, grinding your cannabis plant material to a smaller size will help you save time and money, while extracting the material with better recovery and purity. The moral of the story is that size does matter – and, in this case, small is beautiful!

Acknowledgments

Thank you to Blake Grauerholz at OutCo, San Diego, California, for help conducting the research. Thank you to Barry Schubmehl, Jeff Scott and Günther Crolly at Fritsch, USA, for support in executing the experiments.

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- M Bernberg, "Cannabis Extracts the fastest growing sector on the planet" (2019). Available at: https://bit.ly/2Ub99K3
- B Song, "In an oversaturated market, growers are turning from flower to oil" (2018). Available at: https://bit.ly/3aVD6ng



CALIFORNIA D r e a m i n'

What are cannabis scientists' hopes (and fears) for the industry? The 6th Emerald Conference, 2020 in San Diego, seemed like a great place to find out, so we rounded up three noteworthy speakers to give their assessment of the current state of the art – and their vision for the future.

Robust processing and testing are critical to the development of the burgeoning cannabis industry. With a constantly evolving regulatory, societal, and scientific landscape, successful companies in the space have – through necessity – adopted a forward-looking ethos, and are quick to embrace new technologies and ways of working. Solutions being developed in the cannabis industry may even contribute to advances in other sectors.

The Emerald Conference is an opportunity for technology providers and industry experts to come together to discuss industry best practices and future needs. We sat down with experts presenting and exhibiting at the show to get their take on the future of cannabis science.

GEM OF *a n I d e a*

The year 2014 was a busy one for Wes Burk; he cofounded not only the Emerald Conference, but also instrumentation supply and distribution company Emerald Scientific, and popular proficiency testing scheme The Emerald Test. We caught up with Wes at the 2020 event to discuss the evolution of the conference – and the field.

WHAT LED YOU TO SET UP A COMPANY IN THIS SPACE?

My professional background is as far from cannabis science as you can imagine – I used to work in real estate! But my longtime friend and co-founder, Ken Snoke, has a background in immunology and is a strong advocate for cannabis medicine. Like me, he has an entrepreneurial spirit and we both saw an opportunity emerging in the cannabis industry.

We realized that quality assurance would be critical to the evolution of this industry; if this was going to become a legitimate product we had to prioritize safety, reliability, and predictability for consumers. Unfortunately, even after several states had ended prohibition, the corporations that supply the precision equipment needed for quality assurance would often refuse to deal with cannabis laboratories.

We spotted a gap in the market for an organization that would act as a middle man between the manufacturers of high-quality analytical products and cannabis laboratories that provide safety data to consumers and regulators.

WHAT HAPPENED NEXT?

We went on a fact-finding mission to a major analytical conference, Pittcon, where our concept was met with delight by manufacturers keen to tap into the cannabis market. We also had the fantastic good fortune of meeting a professor from Penn State University, Frank Dorman. We were discussing the chicken and egg problem of setting up a business in this space; you can't get customers until you have something to sell, and vendors won't sell to you if you have no customers. Frank mused that he had seen a startup in a different niche gain recognition by launching a proficiency testing scheme and a technical conference. At that moment, the Emerald Test and Emerald Conference were born!

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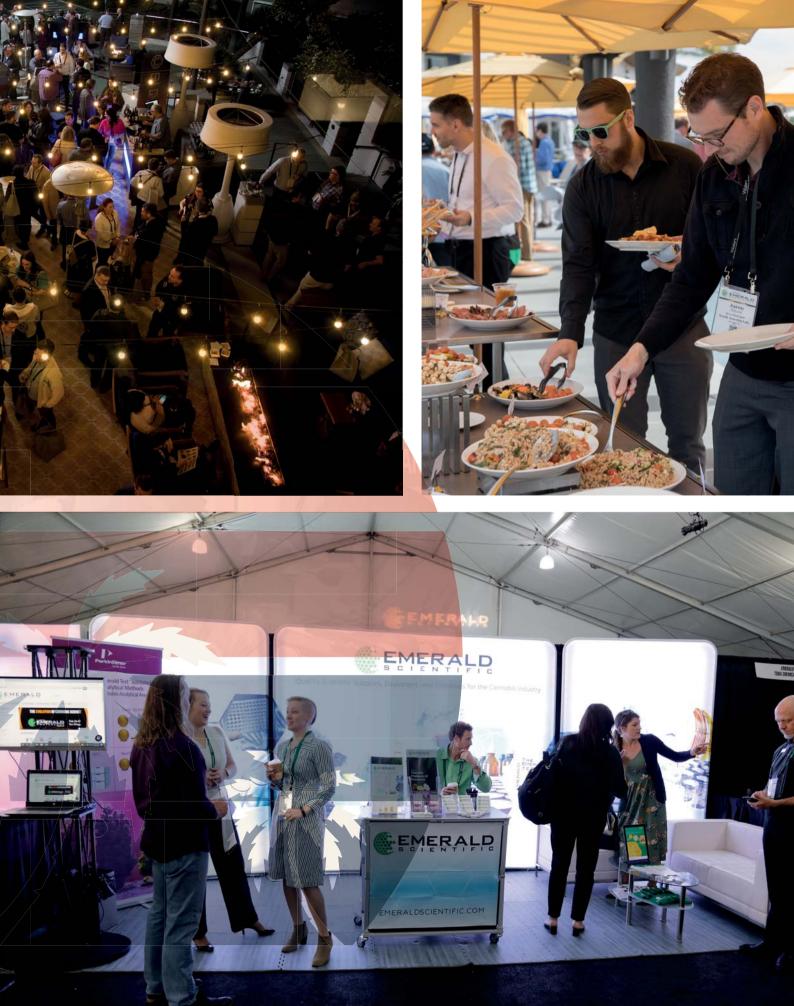


HOW HAS THE SCIENCE PRESENTED AT THE CONFERENCE EVOLVED?

We held the first Emerald Conference in 2014 in San Diego for around 100 attendees and 10 exhibitors. From that first show,

> it was clear there was a desperate need for a platform to share, learn, and collaborate in this space. The pioneers of cannabis extraction and testing felt isolated and there was a general sense that there wasn't much good science out there.

Since then, we've seen a radical maturation of the industry. When we started out we were working with analytical labs running tabletop gas chromatographs in a garage. Now, modern, purpose-built labs are filled with high-end instrumentation. Our first proficiency test in 2014 involved 14 labs taking one test each; now we run it twice a year, and in the last round we had 110 labs participate from around the world, cumulatively taking 605 tests. And the conference has reflected that same change – each year the presentations get more technical and specific.



"Over the last 12 months, we've noticed a real push towards quality."

WHY DID YOU ADD A ONE-DAY QUALITY SUMMIT TO THE EMERALD CONFERENCE FOR 2020?

Over the last 12 months, we've noticed a real push towards quality, with labs keen to meet the standard that other industries are held to. We wanted to offer a forum where we can have an open dialogue to tackle some of the challenges in getting to that point. An issue that anyone in the field will be familiar with is inconsistency in nomenclature. Are crystal, crystalline, and isolate all the same thing? Which name is correct? Hopefully, there will be a white paper resulting from the event, proposing some initial definitions for key terms.

WHAT'S NEXT FOR EMERALD CONFERENCE - AND FOR THE WIDER COMPANY?

The big news for the Emerald Conference is that it will now be run by our longtime collaborators MJBiz Daily. They will continue to tap into our skills in the curation of scientific content, and with their experience of organizing huge events for the cannabis industry, we truly believe the conference will be bigger and better than ever – Emerald Conference 2.0!

For Emerald Scientific in 2020, there will be a focus on nurturing the new Canadian arm of the business, which allows us to better meet the needs of our customers over the border. Another development for us is our partnership with PerkinElmer, which allows us to provide an entire workflow; we can now do a complete build-out from an empty shell to a fully functioning lab, with validated methods and standard operating procedures to go with it. We wanted to take the level of convenience and reliability up a notch for the industry.

ANALYTICAL INSTRUMENTATION IS BECOMING EASIER TO USE - HOW IS THAT BENEFITING CANNABIS TESTING?

It's great that vendors are streamlining workflows to improve efficiency and consistency. For example, the incorporation of AI and robotics is revolutionizing sample preparation. And pocket-sized point-of-use instruments are allowing growers

Cannabis Scientist

to test potency on the fly.

But I do think we need to get the basics right first. One of the problems in this industry has been people wanting to be "in the cannabis space" and starting a testing lab with no background or understanding of what that requires. They buy high-end equipment, but then hire their nephew to run it because he took some science classes in college.

Thankfully, I think the industry is beginning to understand that testing labs are not "plug and play." It's of great importance for consumers to be able to trust the results they're reading on the product label – that is how we get a solid foundation to build a long-term industry.

WHAT ARE YOUR DREAMS FOR THE INDUSTRY?

In the short term, we need an overhaul of the USA government's arbitrary 0.3 percent THC cut-off for hemp versus cannabis. In my view, it serves no purpose and is detrimental to the industry and ultimately to consumers

In the longer-term, I would like to see methods emerging to analyze and group the compounds that influence the user's experience. Currently, consumers are basing their choices on strain names that have limited correlation to chemical composition. Instead, wouldn't it be great if customers were able to say, "I prefer a 1:1 ratio of THC and CBD, with high CBG levels and low levels of pinene?"





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BACK TOBasics

Markus Roggen was voted onto our 2020 Power List, after setting up an independent research laboratory dedicated to optimizing cannabis analysis and processing. Markus tells us about his slightly reluctant entry into the industry, the maddening inefficiencies in current extraction protocols, and his mission to put solid science at the heart of the industry.

HOW DID YOU GET INTO THE CANNABIS INDUSTRY?

Largely by chance! I have a PhD in organic chemistry and in 2014 I was finishing my postdoc in San Diego. I am a keen athlete in my spare time and my triathlon coach encouraged me to stay in the area to keep up my training. "Then find me a job!" I joked; it was unlikely I would find another position in chemistry locally. To my surprise, she came back to me a few weeks later with a potential role – her sponsor, a compounding pharmacy, was setting up a cannabis analytical laboratory and needed a chemist to oversee operations.

My first answer? "Hell no!" I knew nothing about cannabis and had a lot of misconceptions; back then, I thought you smoked the leaves! But friends and family pointed out that it was a legal (and fast-growing) industry in California, so I decided to give it a try. Later, I was headhunted by a vertically integrated cannabis company that wanted to start carrying out extraction and production of manufactured cannabis goods.

GIVEN YOUR INITIAL RELUCTANCE, WHAT HAS KEPT YOU IN THE CANNABIS INDUSTRY?

I'm a research scientist at heart and there is so much to learn in the cannabis industry. In many cases, we don't even know the basics like melting points and solubilities. For a scientist, it is a playground – everywhere you look there is something new to discover!

In this industry, everyone wants to build the largest greenhouse or the biggest extraction facility. Meanwhile, fundamentals like the best light spectrum for cultivation or methods for cannabinoid testing haven't been researched yet. I sometimes joke that my role is: "making cannabis boring again!"

IS THAT WHY YOU SET UP THE INDEPENDENT RESEARCH LAB, CBDV?

Exactly. The cannabis industry is young and a single company



will not be able to sustain a large enough chemical research facility to generate all the data we need. My idea was to build one independent, centralized research facility that can service the whole industry.

Take extraction, for example; right now, most labs carry out decarboxylation using a prescribed method as if it is dictated by a higher power. I wanted to know what method actually worked best. I worked with PerkinElmer to develop a method for inprocess testing of decarboxylation using infrared spectroscopy. We realized that there is a rate difference between cannabinoids and did computational studies to figure out why. Fascinating stuff for chemists, though perhaps not for everyone else!

WHAT RESEARCH QUESTIONS DO COMPANIES BRING TO YOU?

There is only really one question: how do we make it better? For example, we're working on developing better CO_2 extraction. It is a complex process but offers the greatest opportunity because CO_2 – in its supercritical fluid critical state – can be as precise as a scalpel, while ethanol or butane is more like a hammer.

We like challenging questions. Ask us the questions that no-one can figure out!

YOU'VE MENTIONED DATA ANALYTICS - HOW ARE YOU APPLYING BIG DATA TO CANNABIS EXTRACTION?

Let's continue the example of CO_2 extraction. You could set up separate experiments to study the influence of pressure, temperature, and so on, but there are dozens of factors at play and to study the interplay between them you would have to do hundreds of experiments. Instead, we do a design of experiments analysis using historical data from cannabis producers, including thousands of extraction runs. Even at the same facility there is inherent variance in every run, whether they put a few grams more or less in, use different cultivars with different concentrations, or run at 50–100 PSI lower pressure – add data from several facilities and the differences escalate. We can analyze all that variation computationally to understand

how each factor acts alone and in combination to affect the end result – all without having to do a single experiment!

WHAT ARE YOUR HOPES FOR THE FUTURE?

Big data analytics obviously needs big data, so most importantly we want to partner with more companies and share the knowledge we gain for the benefit of the field.

It's starting to dawn on the industry (and the public) that cannabis is not just THC and CBD, or even the 10 cannabinoids we test for. At a previous company, I remember a patient who got a tincture against seizures from our dispensary and was delighted when it worked. But when they returned and bought the same tincture again, it didn't. The concentrations of all the compounds we could analyze for were identical, but the oils were made from two different cultivars. Was there a minor component missing in the second batch? We had no way to know, and neither did the patient – it was deeply frustrating. How can we make consistent products if we don't see most of what's in the product?

At CBDV, we are developing methods of cannabinoid analysis more akin to metabolomics, to help the industry

expand their horizons beyond the major cannabinoids and provide more comprehensive information to consumers.

DO WE NEED NEW TOOLS?

For the most part, no. We just need to make better use of technology and scale-up strategies from other industries. Some equipment may be great in the lab but absolutely unsuitable for large-scale production. For example, crystallization in the cannabis industry often involves... buckets! In the pharma industry, they use crystallization towers that allow continuous recrystallization with very precise parameters to ensure optimum bioavailability.

We also need the right expertise. Classically educated scientists have not typically stepped into the cannabis industry. Often, when a cannabis company says "backed by science," they have one or two chemists with a Master's or PhD. And though that's certainly better than none, it's a far cry from industries like pharma. Plus, when cannabis companies do hire senior scientists from other industries, they tend to choose people with expertise in running large, existing facilities, not developing new processes – so they don't always have the right skills to maximize efficiency. I'd like to see more process engineers enter the industry.





FIRM Foundations

With a background in researching cancer and brewing beer, Andrea Baillo (Green Thumb Industries) hit a hot topic with her Emerald talk on stability testing. We caught up with her to dig into shelf lives, regulatory challenges, and technology tips.

YOU'VE HAD A VARIED CAREER...

Yes, I started out in cancer research, but it was tough to find grant funding in the aftermath of the 2007 financial crash. So when an opportunity arose to work in QA/QC for a brewery, I decided to give it a try. I learned a lot about manufacturing, production, and quality management in the brewing industry, but I was keen to start using my hard-won laboratory skills again, so I was delighted to join Green Thumb Industries as Director of R&D and Quality. The cannabis industry was particularly appealing to me because there's so much left to discover. The industry is evolving at breakneck speed and I thrive on change!

WHAT DOES YOUR ROLE ENTAIL?

There are two sides to my role. First, I help design and formulate new products; at the moment, we're doing a lot in topicals and



edibles. Second, I make sure that we are producing highquality, consistent products by looking at the technology and methods we use in all areas of the business, from cultivation to drug delivery.

A fun project we worked on recently was creating a new transdermal product line. It was great to have an opportunity to engineer a product to deliver cannabinoids through the skin and then prove it using the classic tape strip experiments used to test suncream and other consumer products.

Čannabis Scientist

WHAT ARE THE BIGGEST CHALLENGES FACING CANNABIS PRODUCERS TODAY?

First and foremost, the variation in regulatory standards between states here in the USA. For those of us who serve multiple states, it's a real problem. One state may only allow ingredients on the FDA inactive list, whereas another might have minimal restrictions on ingredients; some states have very low limits on solvents, while others are more realistic. You end up having to make different formulations for different states, which makes supply chains very complicated. Then there is the added issue that moving products across state lines is very difficult – so you need a full suite of production and testing equipment in every state.

Finally, there can be a lack of scientific understanding in the field. In particular, I've noticed that a lot of people working in cannabis don't have the funds to access scientific journal articles, or the skills to scrutinize them. Instead, they just read the abstracts and accept the conclusions unquestioningly – or don't search the literature at all. And that's a shame because there is a great deal of pharmacology research that is very relevant to the industry.

WHY DID YOU CHOOSE PRODUCT STABILITY AS THE TOPIC FOR YOUR TALK AT EMERALD?

Historically, not that much attention has been paid to stability within the industry. Cannabis products are given an expiration date but there has been very little underlying research. Interest has increased in the wake of the epidemic of vaping-related lung disease last year – it has opened people's eyes to the fact that one wrong ingredient could have terrible consequences down the road, so companies want to be sure their products are safe and effective in the long term.

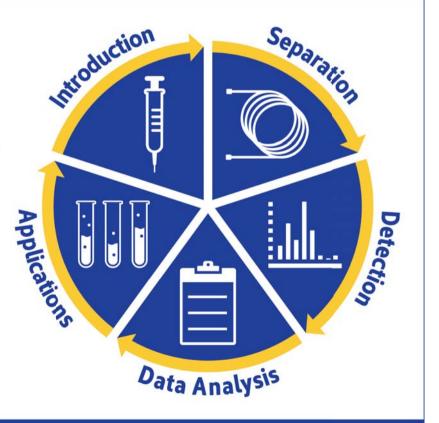
Maryland takes stability seriously, and mandates the maintenance of a retention library. I thought, why not make



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VOX Pops

We took to the conference floor to ask vendors and attendees how they'd like to see the industry evolve...

"The industry is starting to realize that we don't know as much as we thought we did – and we need to work together to come up with solutions. If we start pooling data in the same way scientists do in fields like metabolomics, we'll be able to solve problems a lot faster." Melissa Chandler, Environmental Applications Chemist, UCT Inc, Pennsylvania, USA.

"More data sharing. Everyone talks about sharing data, but few actually share detailed methods." Gerard Rosse, Vice President, Pic Solution, Inc, Avignon, France.

"I'd like to see the trend toward good science in the field continue as legalization expands." Scott Krepich, Industry Marketing Manager, Phenomenex, California, USA.

"In the past few years, we've seen many of the flyby-night labs fall by the wayside, and increasing standardization of processes, especially now that manufacturers are releasing equipment specific to the cannabis market. I'm keen to see this pattern continue." Geoffrey Faden, National Sales Manager, MAC-MOD Analytical Inc, Pennsylvania, USA.

"I hope the industry will move away from hydrocarbon-based extraction and switch to cleaner and greener methods."

Scott Palmer, Chief Scientific Officer, Terpbros, California, USA. our own library alongside the state library? In our library, we now save 30 samples of each product type, allowing us to make multiple measurements over time. We can measure many different aspects of stability: therapeutic (persistence of cannabinoids and terpenes), emulsification, rheology, water activity, water content, chemical modification (for example, oxidation), microbiology, and toxicology (for example, heavy metals leaching from packaging).

We bought incubators to accelerate degradation and allow us to collect more data. We're using this information to monitor the safety and shelf life of our products, and, where possible, tweak the formulation to make it last longer. Now we're developing reports that we can share with the wider industry.

WHAT DATA HIGHLIGHTS CAN YOU SHARE SO FAR?

We were surprised that compressed tablets tend to have lower stability than other products – possibly because we are giving the cannabis a higher surface area, so it's more exposed to oxygen.

WHEN IT COMES TO TESTING STABILITY, IN WHICH TECHNOLOGIES SHOULD LABS INVEST?

One relatively inexpensive piece of equipment I would recommend to every cannabis lab is a water activity meter. There's no intrinsic property more important than water activity in predicting the survival of microorganisms in food products. It worries me to think that some labs might be scrimping on microbiological testing; it would only take a few consumers to become ill and a lot of the progress made to destigmatize the plant could be undone.

If you want to go a step further, near-infrared spectroscopy is an excellent tool for analyzing the major constituents in your product and raw materials.

WHAT TOOLS WOULD YOU LIKE TO TRY OUT

I've got granulation technologies (to allow for more precise dosing) and flash chromatography (to improve cannabinoid separations) on my wish list. Oh – and automated systems to improve speed and consistency.

WHAT WAS YOUR HIGHLIGHT FROM THE 2020 EMERALD CONFERENCE?

My favorite presentation was Jerry King talking about the physicochemical properties of cannabis constituents. He emphasized that the answers are often out there already in other areas of science, and you just need to look for them. That point really resonated with me!

Cannabis Scientist

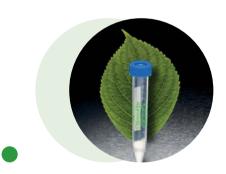
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Homogenization and Characterization of Cannabidiol (CBD) Isolates

By Barry Schubmehl, Jeff Scott, Leos Benes and Dr Günther Crolly

Background

Solid isolates of CBD may be created as a non-homogenous "cake" of material, or as a mixture of loosely associated granules comprising a wide particle size distribution. Creating material suitable for consumption or subsequent formulation in other products typically requires particle size reduction and/or homogenization. Confirmation of particle size distribution of a given sample may be achieved via traditional sieving methods, or by use of a particle size analyzer.

Primary considerations when selecting a milling system for CBD homogenization include:

- Batch size (throughput requirement - kg/batch or day)
- Minimizing losses (physical and/ or chemical)
- Desired final particle size range
- Ease of cleaning to prevent batch cross-contamination

Homogenization - small scale

Small-scale (<1 kg) homogenization of CBD isolate may be achieved by lowenergy ball milling, or by automated mortar and pestle. Batches exceeding 1 kg may be processed in a continuous manner by using the PULVERISETTE 14 classic line variable speed rotor mill, with Cyclone sample collector.

Configured as a continuous milling system, the P14 with Cyclone allows



Figure 1. Inside of a PULVERISETTE 14 rotor mill, showing fixed collection pan, rotor, and sieve ring. High performance Cyclone sample collector in stainless steel is shown on the right. Used together with modified collection pan, the P14 system and Cyclone allow continuous feeding and homogenization of CBD material into the low micron range (consistency of talcum powder).



Figure 2. Left – PULVERISETTE 19 cutting mill system, shown with high performance Cyclone collector mounted to 60 L collection tank. Right – CBD isolate homogenized into the low-mid micron range using the P19 system.

continuous feeding of material, and active removal of material from the rotor area – typically within a fraction of a second. Because the homogenization occurs so quickly and the material is actively removed, there is no time for frictional temperature increase to occur that could cause chemical degradation. Product contact surfaces are stainless steel, or food-grade plastic vacuum hose for the Cyclone, and can all be cleaned thoroughly between batches to reduce the likelihood of cross-contamination. Variable speed motor and range of sieve rings, provides control of particle size output.

Homogenization – large scale

Production-scale (>10 kg) homogenization of CBD isolate into uniform powder can be achieved with the PULVERISETTE 19 Cutting Mill System (P19). Already considered the premier, precision milling solution for preparation of cannabis biomass for extractions, or preroll products, the cutting mill may be

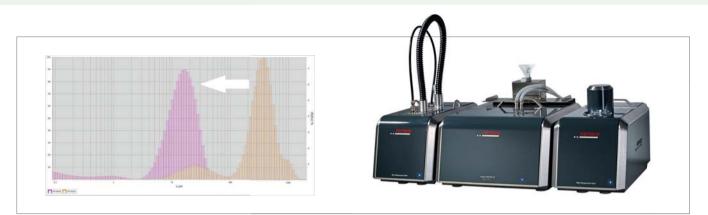


Figure 3. The ANALYSETTE 22 NanoTec was used to measure CBD isolate before and after homogenization. Starting CBD sample (orange) contained a mixture of loose granules with a wide particle size distribution. Material homogenized using the PULVERISETTE 14 classic line variable speed rotor mill (purple) resulted in a particle size consistency similar to talcum powder.

configured as a large-scale homogenizer to allow continuous processing of large (10+ kg) batches of isolate material.

Suggested system settings:

- RPM between 2000 and 3000
- Straight blade or perforated straight blade "Dragon Rotor"
- Gap setting between cutting rotor and fixed knives: 1 to 2 mm
- Sieve cassette: 1, 2, or 4 mm (depending on nature of staring material and desired final size)
- High-performance stainless-steel Cyclone collector

Particle size analysis Characterizing the particle size distribution of a sample may be performed for the following reasons:

- To confirm that a milling system has achieved particles within an accepted range
- In Quality Control: As a criterion for release into the manufacturing process (raw material testing) or for product sale
- In R&D: To study the efficacy of a compound based on its particle size, and/or on the perceived quality of a formulated product

Particle size analysis by traditional sieving methods involves passing the material through a series of sieve pans with progressively smaller openings, and calculating the weight of material that is retained in each pan. Data obtained by using this method is limited by the number of different sieves that are used, and can be confounded if and when particles stick to the metal surfaces. Laser particle size analyzers with reverse Fourier optical system, pioneered and patented by FRITSCH over 35 years ago, have become a worldwide standard across a wide range of industries, for precise size characterization of materials down into the low nanometer range. The ANALYSETTE 22 NanoTec Laser Sizer has been used successfully to characterize CBD isolates, using either a wet or dry dispersion method.

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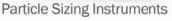


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Sample Dividers

A Deep Dive into Cannabinoid Pharmacology

Sitting Down With... Roger Pertwee, Emeritus Professor, University of Aberdeen, UK. What was your entry point into cannabis research?

I studied biochemistry at Oxford University in the 1960s. During my studies, I had the opportunity to work with the British Army Royal Engineers, which included an army diving course. As part of the safety training, I learned about "rapture of the deep" (also known as inert gas narcosis), a phenomenon in which breathable gases like nitrogen cause feelings of drunkenness when descending below 30 m.

I was fascinated by the idea that the very air we breathe could have such a potent effect and sought out a PhD on the subject with a prominent pharmacology professor at Oxford, William Paton. After my PhD, Professor Paton offered me a postdoc position exploring the pharmacological actions of some of the main cannabinoids and developing standard tests to measure their effects. We extracted our cannabinoids from bottles of a dark green liquid called "tincture of cannabis," still legally sold as a medicine in Britain at that time.

A few years later and newly married, I decided I needed a permanent job and in 1974 I took a lectureship at the University of Aberdeen in Scotland, where I have continued studying cannabinoids ever since.

You are co-discoverer of the firstknown endocannabinoid, anandamide – how did that come about?

It was the early 1990s – the CB1 receptor had recently been discovered and several labs were racing to find the mystery endogenous molecule(s) that would bind to it. My lab had developed an in vitro assay for cannabinoids, based on a similar assay for opioids. We placed the mouse vas deferens, which contains nerve and muscle fibers, in an organ bath and electrically stimulated the nerves to release contractile neurotransmitters; by measuring the resulting contractions of the smooth muscle, we could test the effect of various substances on nerve function. The nerve tissue contains CB1 receptors and, when activated (by adding a psychoactive cannabinoid), they block the release of the contractile transmitters and reduce muscle contractions.

Raphael Mechoulam had isolated a candidate endocannabinoid from pig brain, which he mailed over to me (in a regular envelope – those were different times!). Our assay confirmed that this compound was indeed a ligand for CB1, and the first endogenous cannabinoid to be discovered – a huge breakthrough that breathed new life into the field. A conversation between William Devane, Raphael, and me led us to name the molecule anandamide – ananda is Sanskrit for "bliss or happiness."

An exciting discovery – one of many in your career! What have been some other highlights?

A particularly rewarding experience was working with multiple sclerosis (MS) patients. During the 1990s, a woman with MS wrote an anonymous article describing how she self-medicated with cannabis to control her symptoms. I got in touch with her and she connected me to a whole community of MS patients using cannabis in the UK and the USA. I worked with colleagues in the USA to distribute questionnaires to these patients and we found that their experiences with cannabis were very similar. I believe the resulting paper was a factor behind GW Pharma's decision to pursue research on cannabinoids in MS, which ultimately led to an approved cannabis-based medication, Sativex.

An exciting pharmacological advance came in the mid-2010s when we discovered an important allosteric binding site – a promising drug target – on the CB1 receptor. Allosteric binding sites allow regulation of the receptor. By introducing molecules that bind to this allosteric site and change the conformation of the receptor, we can enhance or weaken "I was fascinated by the idea that the very air we breathe could have such a potent effect."

its responses to cannabinoids. We went on to show that a drug targeting this allosteric site acts as a painkiller in mice – presumably by amplifying the response to the body's endogenous cannabinoids. This makes sense in the context of what we now know about the endocannabinoid system. For example, there is a woman in Scotland with a rare genetic mutation giving her twice the normal level of anandamide – the result is that she feels very little pain, stress, or anxiety.

What has kept you working on cannabinoids for over 50 years?

Partly the fact that there was (and is) so much to be learned, and partly the therapeutic importance. For instance, we still don't know the whole story for plant cannabinoids – there are over 120 of them in the plant, with more discovered each year. That makes it a complicated plant to study but also a treasure chest of potential medicines.

What's next for you?

I'm carrying on my research into allosteric modulators and currently working with a medicinal chemist to explore allosteric modulation of the cannabinoid CB2 receptor. I'm 77 now but I still come into the lab every day, and was traveling regularly to conferences until COVID-19 struck – I often remind myself that my longtime friend and collaborator Raphael Mechoulam is still active in research and he will be 90 this year!



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