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We Need a Bigger Fence

When it comes to (medical) cannabis, why all the side picking?

The current and past of cannabis is full of "sides." Lovers of weed versus haters of hippies. Campaigners for legalization versus those who rally against it. Believers in the potential of the whole plant versus those who seek to isolate and harness individual cannabinoids. Doctors who prescribe versus those who will never be convinced. Those who believe in anecdotal evidence versus those who want hard facts (howsoever obtained). Snake oil peddlers who'll sell us a cure for anything versus entrepreneurs who are more liberal with the truth.

What a divisive plant!

And in the world of cannabis science, some groups of researchers work hard to explore when, why, and how cannabis-based medicines work, while others try just as hard to find the dangers, risks, and side effects. Both avenues are clearly important – but I'm left wondering why they often seem so… separate. Possibly it's a historical lack of support for the former versus more easily obtained funding for the latter (Ziva Cooper offers a hint on page 26).

In the pharmaceutical industry, the concepts of safety and efficacy are deeply ingrained, highly regulated, and tackled by the same (admittedly large and multifaceted) R&D department at most companies. Clearly, there is very little (economic) sense in developing a drug that is either ineffective or unsafe. But it's not quite as clear-cut as it seems. When it comes to a small molecule drug, we're relatively comfortable when exploring – or even predicting – safety profiles. But as drugs increase in their complexity – consider monoclonal antibodies, the recent rise of COVID-19 vaccines, and cell and gene therapies – the word "safe" becomes less well defined. After all, we don't know what we don't know…

Cannabis is also complex. And (human) biology is complex. So I suppose it should come as no surprise that the interaction between the two is furiously debated. (And it doesn't help that modern society appears to be geared towards promoting polarization of opinion.)

Given all the side picking, it delights me when I speak with researchers who exist to simply apply science to the pursuit of the truth – whatever that may be.

There's still much to learn about cannabis in all its glorious complexity. Rather than picking and sticking with a side and allowing unconscious bias to interfere with our choices, aren't we all best "on the fence" for an even bird's-eye view? If so, we're gonna need a bigger fence.

Rich Whitworth
Content Director

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ISSUE 15 - MAY 2021

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Distribution: The Cannabis Scientist is published quarterly by Texere Publishing Inc, 175 Varick St, New York, NY 10014. Single copy sales $15 (plus postage, cost available on request info@texerepublishing.com). Non-qualified annual subscription cost is available on request.

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A United Kingdom on Cannabis?

Perhaps powered by an increasingly legal US market, the medical cannabis engine across the Atlantic appears to be (slowly) building momentum

Despite being legal in the UK since November 2018, medical cannabis can hardly be described as a roaring success. Clinicians are far from wowed by current evidence and bureaucracy takes care of the rest. Not willing to sit idly by, cannabis advocates are addressing both the science and politics that seem to be holding the UK back.

First the science – specifically, the hunger for real-world evidence. In May 2021, Project Twenty21 (T21) – the UK's first medical cannabis registry – published some preliminary findings in Psychopharmacology (1). In brief, 678 patients (64 percent male; average age of 38.7) had already been enrolled into T21 by March 12, 2021. Why? Chronic pain (55.6 percent) and anxiety disorders (32 percent) were the primary presenting conditions; however, the authors noted high levels of multi-morbidity, including insomnia and depression. Most interestingly, the team followed up 75 patients after three months and found that receipt of (legal) prescribed cannabis was associated with a significant increase in self-reported health.

Second, from science to policy, a 16-strong team of experts has sent a strong message – and 10 recommendations – to the UK government. Mainly calling for an end to outmoded red tape, the authors also speak a language politicians may better understand: the medical cannabis market could be worth £2 billion, creating 50,000 new jobs, they say. The full report is free to download (if you don't mind donating a little information): mapletreeconsultants.co.uk/ten-recommendations.

Reference

1. *C Sakal et al., "Developing a real-world evidence base for prescribed cannabis in the United Kingdom: preliminary findings from Project Twenty21," Psychopharmacology (Berl) [online ahead of print] (2021). PMID: 33970291.*

INFOGRAPHIC

Old Data, Worrying Trend

Cannabis use (disorder) and pregnancy by the numbers

4.83 MILLION

Number of live births explored by University of California – San Diego researchers (1)

2.8 → *6.9*

Rise in cannabis use disorder (CUD) diagnoses per 1000 deliveries from 2002 to 2012

BITESIZE BREAKTHROUGHS

The latest biomedical research on cannabis and cannabinoids

Modeling Parkinson's. Cannabis consumption improved motor impairments and changes in synaptic plasticity-related proteins in 6-OHDA-treated rats, leading the authors to call for more research into cannabis and Parkinson's disease (1).

Flying solo. Medical cannabis users aged 50+ are likely to self-treat without healthcare professional consultation, according to the authors of a comparative study (2).

Unexpected rise. Activation of CB1 receptors boosts neurotransmitter vesicle numbers in human synapses – surprising Stanford University researchers (3).

Student views. An intriguing perception study has found – among many other things – that students view cannabis as a less harmful alternative to both prescription medications and alcohol (4).

FM relief? Canadian researchers investigating cannabis use among rheumatology clinic attendees found that fibromyalgia patients were twice

as likely to use medical cannabis, concluding that adjunctive use should be considered for some patients (5).

Synthetic addict. Korean scientists have confirmed the abuse potential of three synthetic cannabinoids – AM-1248, CB-13, and PB-22 – in an intravenous self-administration study in rats (6).

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1. *G Komeili, E Haghparast and V Sheibani, Behav Brain Res [online ahead of print] (2021). PMID: 33961911.*
2. *NG Choi and DM DiNitto, Am J Drug Alcohol Abuse [online ahead of print] (2021). PMID: 33915068.*
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7. *C Lee et al., BMC Public Health, 21, 843 (2021). PMID: 33933061.*

Not for Kids

Digging into the consequences of cannabis and illicit substance use during neurodevelopment

In the Lancet, Child & Adolescent Health, a systematic review of longitudinal studies explores the consequences of cannabis and illicit substance use during neurodevelopment (ages 10–25 years). In particular, the authors wanted to separate out neural predictors from neural consequences – and understand the potential for brain recovery after damage. The review took in evidence from 22 neuroimaging, two neurophysiological, and 22 neuropsychological studies, drawing two conclusions: i) delayed or irregular neurodevelopment in executive functioning – especially emotional perception – was linked to higher frequency substance use, and ii) functional, structural, and cognitive issues were all in evidence after substance use; the degree of harm appeared to be linked to frequency of use, while recovery seemed to be dependent on the duration of use.

"Identifying aberrant neurodevelopment in young people is crucial for preventing substance use-related harm," the authors concluded.

Reference

1. *J Debenham et al, Lancet Child Adolesc Health [online ahead of print] (2021). PMID: 33991473.*

Compared with a matched control group of 40,474 mother–infant pairs, infants born to 20,237 women with CUD were more likely:

TO BE SMALL FOR GESTATIONAL AGE
(OR = 1.13, 95% CI = 1.08, 1.18)

TO BE PRETERM
(OR = 1.06, 95% CI = 1.01, 1.12)

TO HAVE LOW BIRTH WEIGHT
(OR = 1.13, 95% CI = 1.07, 1.20)

TO DIE WITHIN ONE YEAR OF BIRTH
(OR = 1.35, 95% CI = 1.12, 1.62)

References

1. *Y Shi, B Zhu and D Liang, "The associations between prenatal cannabis use disorder and neonatal outcomes," Addiction, [Online ahead of print] (2021). PMID: 33887075.*
2. *UC San Diego Health (2021). Available at: https://bit.ly/3bJj2Xe*

In My View

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

Protagonist or Supporting Act?

Medical cannabis is not a blockbuster drug – the plant should be considered as just one component of an overall therapy or regimen

By Tomas Skrinskas, Founder and CEO, Ascension Sciences, Vancouver, British Columbia, Canada

Imagine going to see an orthopedic surgeon for a consultation on the pain in your knee. You might hope to get it scoped – or think you need invasive surgery. The first thing the doctor will usually tell you? Reduce the stress on the joint; for example, by limiting impact activities or bringing down your weight. We often hope for a quick fix, when we need to consider the root cause of a problem. Why do we expect to simply excise, replace, or cover up the real issue? We find ourselves on a particularly slippery slope in this regard when addressing conditions with cannabis-based medicines. In my humble view, there are two ways in which "problem solving" with cannabis or cannabinoids requires a slight realignment in our collective mindset.

First, we need to understand wellness or health as a process and not as an end-point. I recently heard a leader in the evolving genetic medicine space say, "Taking a pill for an ailment or going to the doctor or hospital isn't 'health care', it's 'sick care.'" In other words, we only go to the doctor when we feel ill. However, the idea of wellness and health in our everyday lives is increasingly important, and many of us are taking supplements, drugs, and cannabis to get well and then keep well. But what happens when we become over reliant on our crutches, neglecting root causes and forgetting to recalibrate? Polypharmacy, for one, is a concern and there might be good reason to take many supplements but it is important to ensure that reason over time.

When maintaining wellness with cannabis, we must remember – however "natural" we deem it to be – that it is exogenous – a foreigner entering your body and altering how it behaves. A case in point: I believe most doctors would not recommend daily consumption of cannabis to improve wellness. Cannabis or CBD – or the next minor cannabinoid du jour – should not be considered health supplements (whatever that means), but medicines with risk:benefit profiles and possible side effects.

Second, cannabis is not the ultimate healer but one helper. Certainly, when it comes to the use of cannabis as a medicine, there are significant medical conditions that can be treated with phytocannabinoids and the whole plant; chronic pain and spasticity associated with multiple sclerosis are just two examples where clinical evidence of symptom relief is conclusive. Moreover, deep research is emerging on subsets of very ill patients and conditions where only cannabis can help (1, 2) – but I worry that the general population may make too many extrapolated conclusions from these reports.

"In truth, we cannot rely on cannabis to heal all our ills equally – or at all!"

In truth, we cannot rely on cannabis to heal all our ills equally – or at all! And so we should keep expectations in check when administering medical cannabis – as a patient or a physician. Especially when it comes to multifaceted conditions, such as anxiety, sleep disturbances, and

mental health, cannabis-based medicines should be a component of holistic treatment. Just as with psychedelic therapies, where guided or supervised treatment is the norm, cannabis and its path to combating a medical condition or its symptoms should include adjunct therapies, such as counseling in the case of mental health or balanced nutrition to address energy or sleep. Too often, people expect a quick cure (or symptom relief) for their ailment without ever addressing the root cause, which may get worse if ignored or might never go away (for example, joints tend to ache as we age, so that knee may always be sore).

In short, cannabis is far from a blockbuster drug. The plant is one potential tool in the proverbial shed that can help move the needle towards health, but the tool must be used properly. I admit to oversimplifying a complex story here – and I consider this a starting point for ongoing discussion (feel free to comment below).

I hope I am not overstepping any boundaries; rather, I want to shed light on the notion that we all have the potential to lead healthier lives by being more self-aware, taking everything in moderation (even moderation), and asking ourselves often about what drives us to make unhealthy choices.

Don't Cross the Streams!

We need a clearer distinction between medicinal, medical, and pharmaceutical cannabis products

By Miguel Fagundes, Chief Technical Officer (CTO), Botanical Holdings, London, UK

People have been busy writing a great deal about cannabis and cannabis-derived products for the last few years. As you hack your way through the jungle of information, you will not only find medicines intended for prescription by doctors (for example, Epidiolex and Sativex) but also so-called "self-medication" products, including edibles, cosmetics, and dietary supplements. Such products can be directly sold to a consumer without a requirement for a prescription from a healthcare professional. Notably, the amount of CBD in these products is typically far lower than the concentrations found in clinical trials. Patients and consumers should also be aware that these widely available CBD products may not meet strict quality assurance guidelines as they are not regulated as medicines (regardless of their claimed wellness benefits) – and sometimes there is no specific legislation for products containing CBD...

Though there are major differences in the developmental and regulatory paths for cannabis-based prescription drugs and cannabis products developed for self medication, I think it is important to emphasize how little clarification has been provided to the public, patients, and even to the wider medical community.

Non-medical or "self medication" products are legally required to have a THC or psychoactive content below around 0.2 percent in the EU or between 0–5 percent in the USA, depending on the state. As with other herbal remedies, the declared contents of non-medicinal CBD preparations are variable, and often inaccurate.

Let's clear up some definitions. In my view, medicinal cannabis refers to both "medical" and "pharmaceutical" cannabis products. Medical cannabis is taken to mean plant-based or plant-derived cannabis or cannabinoid-containing products/preparations – either prescribed by a medical practitioner for the treatment of a specific condition or disease (for example, epilepsy, pain, multiple sclerosis) or purchased by consumers without prescriptions for medical purposes. By contrast, pharmaceutical cannabis refers to products that are formulated or processed using cannabinoids (natural or synthetic) that have been through full clinical trials and licensed as a medicine with marketing authorization; such drugs typically require medical prescriptions (for example, Sativex, Marinol, Syndros, and Cesamet).

Some of us have a clear understanding of the difference, so why do patients and consumers find themselves in such confusing times? Well, given increasing signs of therapeutic usefulness and with relatively undefined regulatory pathways, a number of companies raced to become leaders in the medical/medicinal cannabis market, happily blurring (or brushing out) the lines along the way. This "green rush" has left us with two big questions: to what extent was this early race won at the expense of quality, safety, and efficacy issues? And have these trailblazers damaged the reputation and credibility of the cannabis industry as a whole?

I think it is high time the cannabis community made a clear and unbiased distinction between very different types of cannabis products – cannabis is not one thing. Once we've made the distinction, we need to agree on regulatory frameworks that protect patient safety in all cases. But what would that regulatory framework look like at a global level?

Despite centuries of widespread cannabis and cannabis-derived product use, we have a long way to go in terms of harmonizing the legal and regulatory framework across the globe. For example, understanding the regulations that must be applied to a specific primary processing stage (or even drying of the cannabis plant) is of paramount importance, yet interpretations of such regulations can differ significantly between countries.

And yet, complaints and confusion aside, the future facing among us agree that more and better testing at all steps in the cannabis product supply chain is optimal for patient safety – again, whatever the product type. Therefore, it is unfortunate that a dearth of reliable testing companies compounds the problem!

We need more accredited laboratories with staff experienced in GLP, ISO, or GMP. Also, implementing a proper quality management system is key to efficiently address all the tasks related to documentations, testing, calibration, training, and so on. ISO/IEC 17025 is written to give an overview for testing and calibration labs; however, it lacks specifics. Figuring how the standards apply on a day-to-day process is something that can only be achieved by staff with the right training and background.

At the same time, we should not allow manufacturers to lead the show; health agencies must be the drivers of regulation and offer appropriate technical oversight. If they do not, we will end up with ambiguous standards and a lack of uniformity, which promote unsubstantiated, non-scientific and often blatantly false claims on product safety and efficacy. Cannabis is medicine so it should be tested like medicine with the right validated methods.

If we want the cannabis industry to be successful, we must all strive for uniformity and alignment – and that demands a joint effort between the different organizations and agencies around the world. We must work together to develop a comprehensive regulatory framework and then standardize manufacturing, testing, and, last but not least, labeling of cannabis products for both medical and medicinal markets.

And if companies can't get on board for the benefits of patient safety, then consider that regulations and testing also drive quality. Consider this: consumers and patients alike ultimately vote with their loyalty and money – and unmet expectations (medical or otherwise) caused by quality issues are very likely to put your profit margin at risk!

What's the Deal with Synthetic CBD?

The future of cannabinoid manufacture lies not in natural plants but in chemical... plants

By Richard O'Halloran, CEO, Biosportart, London, UK

As scientists, you'll likely be aware that your morning vitamin C tablet does not originate from a lemon grove on some sunny Sicilian hillside. But what about consumers? Do they know that their "natural" supplements come from a chemical plant and not an actual plant? And, if it's efficacious, safe, and cheap, do they care? The industrialized reality is that many naturally-occurring chemical compounds, including ascorbic acid, can be produced far more efficiently (and at potentially lower cost) than their natural equivalents.

And few (naturally-occurring) compounds have generated as much interest – or shown as much therapeutic promise – as the cannabinoid CBD. So it should come as no surprise that CBD is the next "supplement" set to be overtaken by a synthetic revolution.

Some surveys estimate that one in three people in the US have tried CBD and up to six million people in the UK are self-medicating with CBD products to help with diverse problems, including anxiety, insomnia. and chronic pain. And yet the quality and content of cannabis-based products are often unknown – and some products are even illegal or potentially dangerous. Why? Because plant-derived products are impure by their very nature, containing contaminants, such as pesticides, and other (unwanted) cannabinoids, such as THC, and even unnatural cannabinoid degradents, depending on the extraction process.

Growing cannabis at scale is more an agricultural than a scientific endeavor; small environmental variations can lead to large differences in plant quality, purity, and cannabinoid yield – this is not news to the industry. Cannabis is also particularly effective at absorbing lead, cadmium, and nickel from the soil, which is great for environmental remediation, but certainly not when it comes to selling food and cosmetic products.

Synthesis is currently the only way to meet strict (albeit unenforced) European requirements on cosmetics ingredients (which do not permit origin material that is illegal in any member state) or to meet

specific institutional requirements, such as those from the World Anti-Doping Agency (which prohibits all cannabinoids except CBD, in any amount).

Following these trends, and as quality and safety regulations for the CBD industry are further developed and implemented for the consumer market, synthetic CBD is becoming an increasingly appealing alternative. I'd like to reiterate an important point: high-quality synthetic CBD is chemically identical to naturally-occurring CBD. Referred as bio-identical or nature identical, depending on the market, synthetic CBD is now the dominant base material against which naturally occurring CBD purity is tested.

Why the need for reiteration? Unfortunately, synthetic cannabinoids have garnered a great deal of bad press thanks to synthetic analogues (think: "spice"!) that act upon the same receptor but do not occur in nature. Thankfully, (known) cannabinoid analogues are illegal, but their existence has given the synthetic CBD sector somewhat of a marketing headache...

But where does synthetic CBD come from? Well, in the case of biotechnology company PureForm Global, the starting base material is actually a citrus terpene, while high-flying Cellular Goods are touting future commercialization of CBD via a biosynthetic route (a form of fermentation).

Though pathways in CBD synthesis vary and other cannabinoids (including THC) can be accidentally produced, a number of manufacturers are now producing CBD without any detectable unwanted cannabinoids. Such purity is better for consumers (especially those subject to professional testing) and for formulators, who can put greater amounts of CBD in products without risk of exceeding the assumed limit of 1 mg per container.

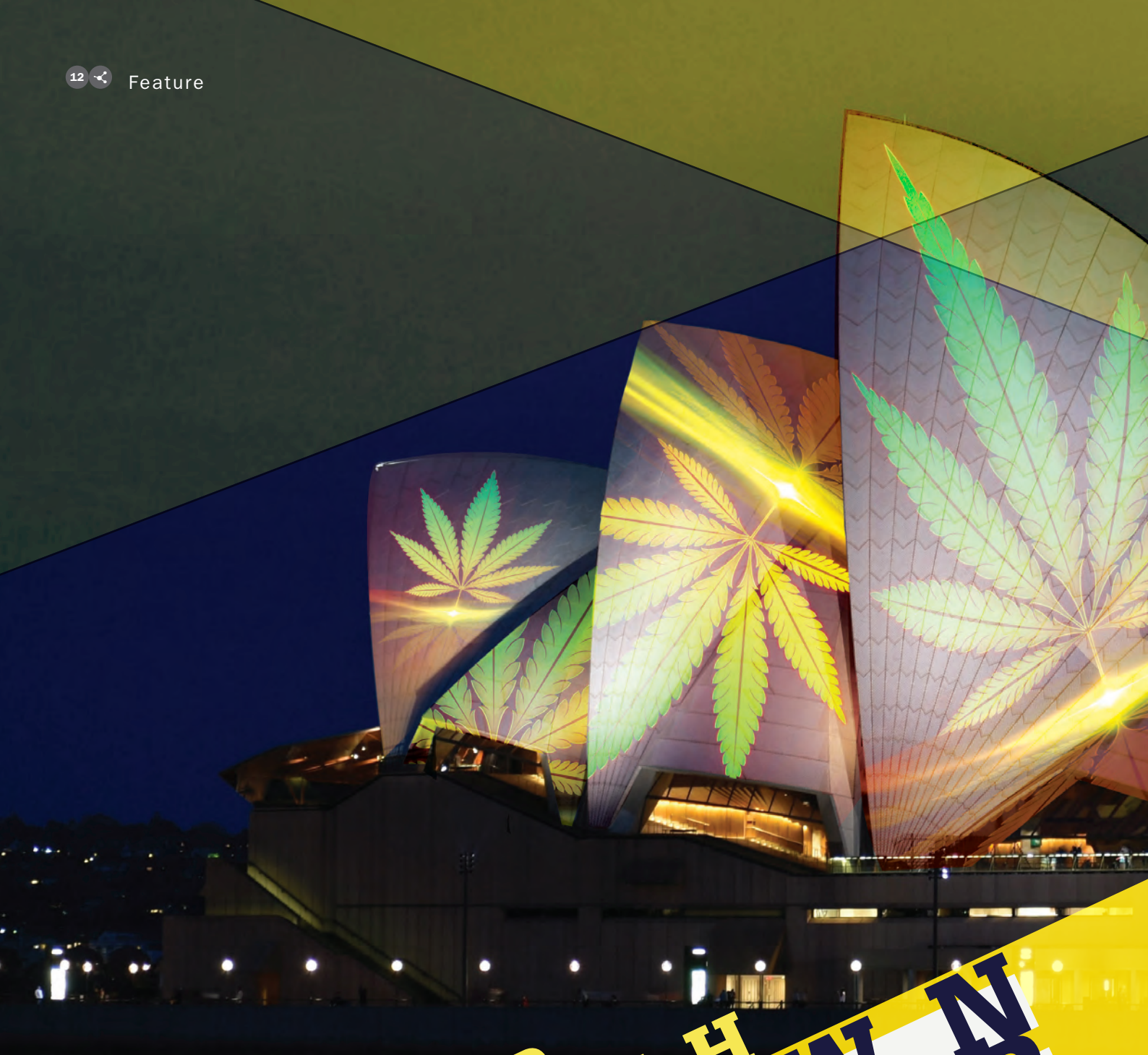
For many people, words like "plant/herbal extract" and "natural origin" sound better or safer – for humans and the environment – than "chemical synthesis." But the synthetic route – at least for CBD – actually uses fewer chemicals than solvent and gas extraction, making it more eco friendly. There is also no need for fertilizers or pesticides – and thus no risk of residues. And there is no risk of dangerous, potentially cancer causing mycotoxins, which is an ongoing challenge for cannabis growers everywhere. All good for humans. In addition to being purer, each batch is consistent, free from pesticides, and traceable.

Right now, despite the advantages of synthetic CBD, the vast majority of products contain plant-derived CBD – and, especially for those stated to be "broad spectrum," these are highly likely to contain THC in trace or greater amounts (not to mention the other known and unknown impurities). In my view, if we're thinking about CBD as a health and wellness product, this needs to change.

My view is clearly shared by the EU, who have already rejected multiple Novel Food applications from hemp growers (the application deadline for CBD brands looking to gain Novel Food certification was March 31, 2021). And though products with an application submitted were allowed to remain on sale from April 1, who knows how many of these products will meet the Food Standard Authority's (FSA) strict requirements? It is Biosportart's view that synthetic producers of CBD that follow clear manufacturing and testing protocols, such as PureForm Global, have a serious upper hand when it comes to achieving full Novel Food status from the FSA.

Don't get me wrong, *Cannabis sativa* is an amazing plant. It has co-evolved with mammals for millions of years and contains a whole suite of interesting, interacting chemicals – the full potential of which we are just beginning to understand. Indeed, we are only now emerging from what could be described as the "dark ages" of cannabis; for so many years, social stigma and a strict legal environment have prevented the plant's incredible benefits from being extracted, researched, and applied.

But as we begin to understand the benefits and side effects of individual cannabinoids, the industry must evolve and mature. In my view, CBD synthesis solves many challenges and provides the means to achieve purity, consistency, and yields at a scale that allows adoption of CBD for a wider variety of consumer and medical applications, unlocking just one beneficial aspect of this incredible plant.



RESEARCH DROWN UNDER

Iain McGregor, Director of The Lambert Initiative for Cannabinoid Therapeutics, University of Sydney, Australia, shares his research, opinions, and vision.

What sparked your interest in cannabis research?

To answer that, I'd have to rewind all the way back to my youth, when Edinburgh was flooded with hashish from Afghanistan and Pakistan. As a musician I saw a lot of drug-taking – and I was curious as to how a drug like cannabis could affect behavior. I was lucky enough to gain entry to an undergraduate degree in experimental psychology at the University of Oxford, where I focused my studies on the brain and its circuits. At that point, thinking back to my earlier fascination with how drugs affect behavior, I became interested in the pharmacology and neural effects of drugs like cannabis.

After graduating in 1983, I spent three years in the music industry playing in a succession of dodgy bands – none of which I am prepared to name! My music career wasn't taking off and Thatcher's Britain was looking bleak, so when an opportunity came up to do a PhD in psychopharmacology at the University of Sydney, Australia, I jumped at the chance.

What were you working on back then?

The 1990s was an exciting decade for the cannabinoid research community, with the discovery of the cannabinoid receptors and the first endocannabinoid, but legal restrictions made it tough to access THC and other cannabinoids for research. My first publication on cannabinoids was in 1996, after we got hold of a little bit of a potent synthetic CB1 agonist called CP 55,940 from Pfizer. That allowed us to interrogate the CB1 receptor and do some of the first work looking at the behavioral effects of CB1 agonists in rats.

I then did some work on how THC differentially affects the adolescent brain. We also discovered the phenomenon of THC re-intoxication. THC is stored in fat and if that fat is then rapidly metabolized, the THC can be released back into the blood. We first showed the effect in rats, and later by getting people who were heavy cannabis users cycling furiously on exercise bikes! That work became relevant later when I was asked to testify in court on behalf of people who have failed drug tests for THC. One example was an overweight man who had been using cannabis heavily but, on probation for another offense, decided to get his life in order and got a job as a builder's laborer, only to repeatedly fail court-mandated drug tests. I gave evidence that the extremely physical work he was doing could have triggered the release of fat-stored THC from previous drug use into his system, and he was spared jail.

"We're collaborating on a trial with Tourette's syndrome patients up in Queensland and another for insomnia in Sydney, using a full-spectrum oil with THC and a range of terpenes."

How easy is it to do research on cannabis in Australia now?

It's recently become a lot easier. The government introduced a medicinal cannabis scheme for patients in 2016 and, as part of that legislation, cannabinoids have been rescheduled and have become easier to access for research. We still have to complete a mountain of paperwork, but it's probably less troublesome than in the USA, where even CBD has been treated like plutonium when used in preclinical research. We also have a mature health system in Australia with good infrastructure for clinical trials – and we have been spared the worst ravages of COVID (fingers crossed).

Could you share some of the clinical trials you are doing at the Lambert Initiative?

We're collaborating on a trial with Tourette's syndrome patients up in Queensland and another for insomnia in Sydney that use a full-spectrum oil with THC and a range of terpenes. We are also about to embark on several high-dose CBD trials, particularly focusing on pain. Many people are using CBD products for pain, but there's very little evidence in the human literature that it is effective. In particular, we have a large trial on pain in spinal cord injury patients about to start; we want to see whether CBD can ease neuropathic pain resulting from the injury. We're also running trials on CBD and alcohol detoxification and methamphetamine addiction and also seeing whether it increases exercise endurance and enjoyment. Like many scientists, we're also very interested in looking beyond CBD and THC, and have human trials planned for some novel phytocannabinoids.

The Lambert family with members of the Lambert Initiative

The Quadrangle,
University of Sydney

Meet (some of) the Lambert team

Jonathon Arnold, Associate Professor and Deputy Director

Why I pursue cannabis/ cannabinoid research...

I decided to pursue cannabinoid research 25 years ago because, at that time, huge discoveries were being made on the endogenous cannabinoid system. For a pharmacology major it was mind-blowing that a new lipid signaling system was identified in the brain and body, and that it was through this system that cannabis produced its mood-altering actions. My first projects examined the behavioral pharmacology of THC, anandamide, and the synthetic cannabinoid CP 55,940 – a molecule that had been used to map cannabinoid receptors in the brain for the first time. I remember attending the International Cannabinoid Research Society meeting in 1997 and witnessing Nephi Stella present on the effects of 2-AG on neuronal plasticity – and having the late William Devane, discoverer of anandamide, crash in our room! These were exciting times to start a research career in cannabinoid science!

What I'm working on...

The Lambert family saw the great benefit that medicinal cannabis had on Katelyn Lambert – who suffers from Dravet syndrome – an intractable form of childhood epilepsy. From this personal experience, the Lamberts gave a huge gift to the University of Sydney to help advance cannabis science and unlock the medicinal potential of cannabis. Over the last five years, we have been testing single molecule phytocannabinoids and full-spectrum extracts to tease out which cannabinoids or combination of cannabinoids have therapeutic effects in preclinical disease models. We have discovered several phytocannabinoids beyond CBD that possess anticonvulsant properties, with some that appear as potent or even more potent than CBD. For example, several minor cannabinoids (CBC, CBCA, CBCVA, CBGVA and CBDVA) have been identified as anticonvulsants (4, 5);while the phytocannabinoid acids CBDA and CBGA reduced seizures at lower doses than CBD. We also found a cannabis extract that has anticonvulsant properties, which we are now deconvoluting further. Could there be a magic combination of molecules or could there be an anticonvulsant constituent we have not yet considered?

Where we're heading...

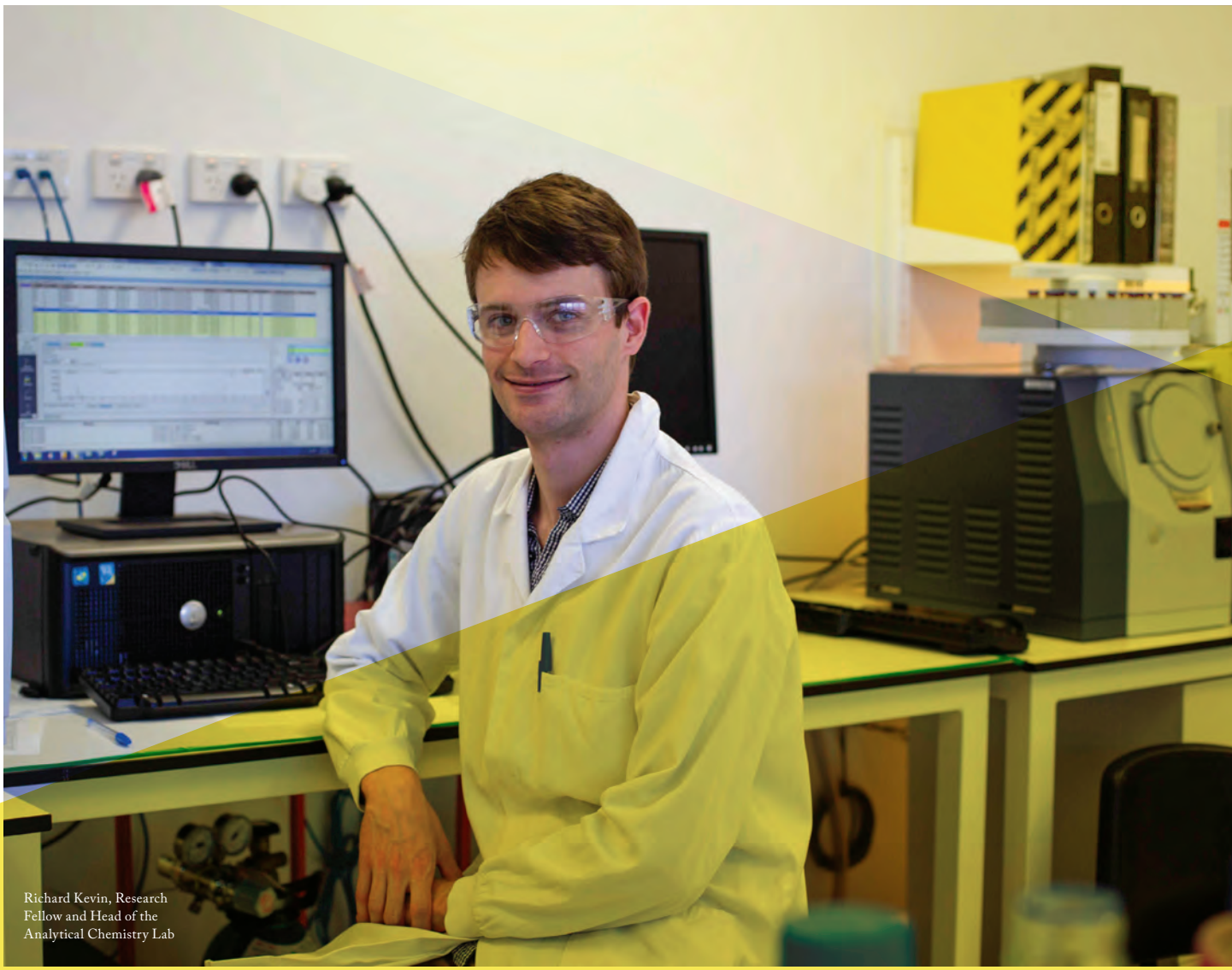
I hope my research brings innovation to the field of medical cannabis and ultimately the very best cannabis-based medicines to patients. Our team brings together expertise in medicinal chemistry, analytical chemistry, in vitro and in vivo pharmacology, human psychopharmacology, and clinical trials. I hope to support this next generation of cannabis scientists to help bring about the next big discoveries in the field of cannabis science.

What's the story behind the Lambert Initiative? How did you get involved?

The story starts with Lucy Haslam, a former nurse and an important advocate for medicinal cannabis compassionate access in Australia. Her son was dying of cancer, wracked with pain, and had no appetite. Cannabis was one of the few things that helped him but back then there was no way to access the drug legally. Lucy's husband, a drug squad detective in a small country town, ended up buying weed on the black market. Lucy was outraged that they had to break the law to get help for their son, and set up an organization called United in Compassion to campaign for drug law reform.

Where do I come in? In late 2014, Lucy set up a symposium about medical cannabis and I was invited to speak, along with my colleagues David Allsop and Nicholas Lintzeris. In my talk, I floated the idea of an Australian Center for the Study of Medicinal Cannabis. Afterwards, we were approached by Michael Lambert, whose daughter Katelyn suffers debilitating pediatric epilepsy and was being treated with (then illegal) CBD oil.

A couple of weeks later, we got a call out of the blue from Michael, who told me that he'd been discussing the idea of a



Richard Kevin, Research Fellow and Head of the Analytical Chemistry Lab

Samuel Banister, Team Leader in Medicinal Chemistry

Why I pursue cannabis/ cannabinoid research...

I've always been fascinated by nature as a master chemist. More than two-thirds of the medicines we use have some heritage in the chemical space of natural products. Medicinal chemistry allows us to rationally modify these natural molecules, atom by atom, to improve their ability to treat human diseases. Cannabis represents a treasure trove of interesting chemical matter for the discovery of new medicines – and most of it is unexplored!

What I'm working on...

Our lab is focused on the development of new cannabinoid-based treatments for specific forms of epilepsy. We are investigating various chemical strategies for improving cannabidiol as a treatment in forms of epilepsy, such as Dravet and Lennox-Gastaut syndromes. This approach uses rational modifications of CBD that are expected to improve potency and reduce side-effects by decreasing lipophilicity and increasing engagement of several key targets. We are also exploring the potential of several minor cannabinoids, such as cannabichromene, to modulate targets known to be important in many forms of epilepsy (1). Both of these programs will offer insights into the key receptors and signaling pathways relevant to the antiseizure effects of cannabinoids, enabling the development of next-generation cannabinoid treatments for epilepsy.

Where we're heading...

It's been exciting to watch the explosion of cannabis biotech companies over the past several years – everything from synthetic biology companies focused on the commercial manufacture of rare and exotic cannabinoids to start-ups using cannabinoid chemotypes or the endocannabinoid system for traditional drug development in new indications. There is a huge amount of exciting chemistry happening in the cannabis space right now.

research institute with his father, financier Barry Lambert, and asked if we would like some money for our center... Barry and Joy Lambert went on to pledge 33.7 million Australian dollars over 10 years to create the Lambert Initiative. All too often, scientists are locked into 6- or 12-month projects but, when it comes to drug discovery – or making a material difference in medical research – that's simply not long enough. It's a dream come true for any scientist to get an opportunity like this, particularly in such an exciting field. And we're forever grateful to the Lambert family for making it possible.

How did you set about launching the Initiative?

Though such funding is an amazing opportunity, it is also an awesome responsibility. All eyes are on you – and you get a bit of snarkiness from some of your fellow scientists at times. There is an overwhelming weight of expectation. The first two years were spent getting our lab properly equipped and developing a research strategy. During that time, we lost Dave Allsop to esophageal cancer – a terrible setback for us personally and for the project, which Dave was at the heart of.

"The first two years were spent getting our lab properly equipped and developing a research strategy."

But, despite this difficult start, we pulled together and got the Lambert Initiative off the ground. Now, we've got around 30 staff and students in a purpose-designed facility, doing all sorts of interesting work, ranging from medicinal chemistry through to cell assays, animal models, and clinical trials, plus a great deal of advocacy, political, and regulatory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work. We take education seriously and often appear in the Australian media as a trusted authority on the science of cannabis. There's never a dull moment!

Where do you want to be at the end of the initial 10 years of funding?

The most important goal is the development of novel cannabinoid therapeutics. As well as carrying out clinical trials with CBD, THC, and various minor cannabinoids, we are working to develop novel medicines. Our model is to take phytocannabinoids, tweak their structure and bioavailability, and develop a huge library of molecules – over 700 and growing. Samuel Banister is our medical chemistry team leader, and he has an incredible ability to take a chemical structure and embellish it.

We've got a lot of information around the main targets that phytocannabinoids engage with in the body, and we use that to match cannabinoids with potential disease states. We then engage with a whole host of external phenotypic modeling labs to perform high-throughput screening of our library of cannabinoids for activity against a certain disease. For IP reasons, we can't always shout about our findings, but we're working away behind the scenes and very excited about the future.

We also do a lot of public-facing work in advocacy and public policy. Getting a novel drug to market carries poor odds, so we feel it's important we contribute in other ways too. We recently played an important role in making CBD available over the counter in Australia. We also do a lot of outreach to those Australians who are still using illicit cannabis products to self-medicate, which is a majority, as regulated products are still very expensive.

One study I'm really proud of (led by Anastasia Suraev) involved working with families who were medicating their epileptic children with black market cannabis oil (3); we tested their oil for cannabinoids and contaminants. It was helpful for the families to know what was in the products they were using, but it also gave us several interesting leads on minor phytocannabinoids; for example, CBC appears to have a

Elizabeth Cairns, Postdoctoral Researcher

Why I pursue cannabis/ cannabinoid research...

I became interested in the endocannabinoid system during my PhD, while under the supervision of Profs Melanie Kelly and William Baldridge at Dalhousie University. Prof Kelly is an expert in the ocular endocannabinoid system and targeting of this system for therapeutic use. I find it fascinating that even though the endocannabinoid system seems to be involved in almost every physiological process, there is still so much that we don't know about it. My main interest is in how we might leverage the endocannabinoid system and cannabinoids to treat different disease states. I am fortunate to continue this work at the Lambert Initiative, within a team that has such a wide range of expertise.

What I'm working on...

In general, my work focuses on screening cannabinoids and endocannabinoid system modulators in various models of disease from both top-down (disease-focused) and bottom-up (target/cannabinoid-focused) approaches. In addition to examining the use of cannabinoids and endocannabinoid system modulators for the treatment of neurodegenerative diseases (both in vitro and in clinical studies), I also have several collaborative projects spanning across various disease areas, such as cancer and inflammatory bowel disease. Simultaneously, I am also involved in projects uncovering the pharmacological actions of phytocannabinoids beyond the classical cannabinoid receptors, in an attempt to explain some of the reported effects in humans and/or discover new possible therapeutic utility.

Where we're heading...

Through our systematic and rigorous work, I hope that we can advance the understanding of the endocannabinoid system and the function of cannabinoids to establish where cannabinoid therapies could best be used. By establishing a sound knowledge base and through directed policy work, I hope we can help provide clear answers for patients and their healthcare practitioners – and continue to improve patient access to beneficial treatments.

Iain McGregor and the Lambert Initiative's latest PhD graduate, Tom Arkell

Anastasia Suraev, PhD candidate and Clinical Research Officer

Why I pursue cannabis/ cannabinoid research...

What drew me to cannabinoid research was my prior research into the impact that uncontrolled seizures can have on cognitive development, particularly when the seizures begin at a very young age. Epilepsy is more than just seizures. It can affect the child's thinking skills, behavior, language, social interaction, and physical functioning. It speaks to the complex nature of this disorder and the need for new and better treatments, particularly for those who have tried everything and are out of options. This reality spurred my interest into the clinical applications of cannabinoids in treating multiple aspects of epilepsy and other chronic and refractory health conditions.

I have been working on a range of clinical projects with the Lambert Initiative for Cannabinoid Therapeutics since 2016 – with a particular research focus on epilepsy (3) and sleep disorders (4).

What I'm working on...

I am currently working on the 'CANSLEEP' trial which is a randomized, placebo-controlled, crossover study that investigates the effects of CBD and THC on sleep and daytime function in patients with chronic insomnia. It is the first study of its kind to use a novel neuroimaging technology known as high-density electroencephalography (EEG) to comprehensively examine changes in brain activation during sleep and while awake in this population. We are also assessing next-day residual effects on cognition, alertness, and driving performance.

This work will provide insights into how cannabinoids affect the brain during sleep and the next day in a manner that will hopefully help to inform policy, research priorities, and clinical decision-making.

Where I'm heading...

I aspire to become an internationally recognised expert in my field and conduct high-quality clinical research that will help to bring medicinal cannabis out of the dark and legitimise it as a viable treatment option.

strong anticonvulsant effect. The study shone a spotlight on the desperation of these families and contributed to pressure on the government to ease restrictions on cannabis products.

What recent studies have been exciting?

I was also delighted with the paper (led by Tom Arkell) we put out in December 2020 in JAMA, which was the first ever study of whether CBD affects real-world driving (5). We showed conclusively that vaporized CBD had no impact on driving, whereas THC caused impairment for around 4 hours. We also recently carried out a meta-analysis (led by Danielle McCartney) of every study done on the duration of THC impairment (6). Studies like this won't help us get a new drug to market but are incredibly useful for authorities, for politicians, and for patients. It's one of the most asked questions about medical cannabis – how safe am I to drive? And now we'll be able to give a pretty clear answer.

What is the best part of your job?

Probably the thing I enjoy most, in a social sense, is getting to know the brilliant people in our group and helping them succeed. I love it when people on the team do great work, regardless of whether I'm personally involved or not. If we provide an environment that enables the next generation of cannabinoid scientists, then I know I'm doing my job right.

The second thing that I really enjoy is what you might call the game of science – embarking on a research project and waiting to find out if the result will be what you expect or something totally different. If you're very, very lucky, you'll set out on a voyage to a particular destination and end up somewhere completely different and even better. I find that game so enjoyable, so compelling. And my current role lets me play on multiple levels – from chemistry to clinical trials to regulation. Though I'll admit it can make for a few sleepless nights – especially when you're planning your next moves or wondering how you're going to get past an obstacle. Like most people in leadership positions, I sometimes wonder if I'm the right person for the job. But overall I love it!

What is your current focus?

One thing that I'm thinking a great deal about at the moment is strategic planning: how can we best use our cannabinoid science to best alleviate human suffering and how do we more rapidly translate from our high throughput cellular work into meaningful clinical outcomes? I also spend a lot of time thinking about how Lambert can continue into the future beyond our funding window that ends in mid-2025. Building this thing has been quite an achievement (and one that I can only take a small part of the credit for) and I hope it continues far beyond 2025. Whether that involves leveraging further philanthropy, spinoff companies, or grants is something I give a lot of thought to. After all, in many ways, it's only just getting started.

What's next?

Australia has now approved over the counter CBD at doses up to 150 milligrams per day. So one of the clinical trials we're doing this year is looking at whether low-dose CBD does anything useful. Currently, there is very little evidence on whether a 25 or 50 milligram CBD capsule has any impact on health. No one has done those clinical trials. So we're doing a trial – affectionately known as the "grumpy" trial – in which middle aged people with insomnia take CBD or placebo for 12 weeks. The primary outcome is insomnia, but we'll also look at mood and anxiety, cognitive function, metabolic function, even susceptibility to minor illnesses. I've got my own vision of what the outcome is going to be. But perhaps nature has got other ideas!

Have you tried CBD yourself?

I use it for one thing: tennis. I take a CBD capsule before I play tennis because I feel that it just makes me less anxious about the outcome and therefore able to play more confidently. It may well just be a placebo effect, but then the placebo effect is a very powerful thing…

Danielle McCartney, Clinical Research Fellow

Why I pursue cannabis/ cannabinoid research...

I first became involved in cannabinoid research when the Lambert Initiative offered me a position studying the effects of cannabinoids on driving performance. Before this, most of my research had focused on the effects of alcohol consumption – and I was excited about the prospect of expanding into a new field. One of the things I've enjoyed most about this field is the scope that exists to bring about positive change; for example, to improve legislative approaches to identifying and prosecuting cannabis-impaired driving.

What I'm working on...

Much of my research focuses on understanding the manner in which cannabinoids affect driving performance. Right now, my colleagues and I are particularly interested in the effects of prescribed medicinal cannabis. Patients using prescribed THC-containing medicinal cannabis products are not permitted to drive and face potentially severe penalties if caught operating a motor vehicle with "legal THC" in their system. And yet it is unclear whether these individuals are actually impaired. In fact, we suspect they may develop tolerance to THC's effects (6) and that the alleviation of medical conditions, such as chronic pain, PTSD, depression, and insomnia could even assist driving. I have also been involved in other projects investigating CBD's effects within the context of sport and exercise. Indeed, my earlier PhD research looked at different nutritional strategies to enhance post-exercise (7) recovery and athletic performance. Some of our recent data suggest that CBD is unlikely to impair (and could, in fact, aid) exercise performance. Knowing this, we are planning to investigate its utility in the treatment of sports concussion. Despite the high prevalence and harmful effects of sports concussion, there is limited evidence to support current rehabilitation strategies.

Where we're heading...

I hope that our research can help improve legislative approaches to identifying and prosecuting cannabis-impaired driving. I am also excited to begin our research in the field of sports concussion and hope that this generates some interesting results!

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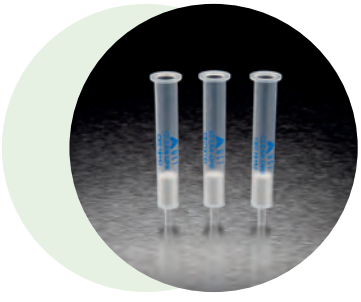

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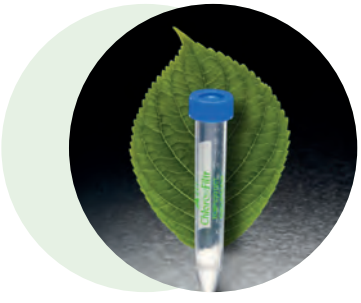

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Found in Translation

Sitting Down With… Ziva Cooper, Director of the UCLA Cannabis Research Initiative in the Jane and Terry Semel Institute for Neuroscience and Human Behavior, and Associate Professor in the Department of Psychiatry and Biobehavioral Sciences and Department of Anesthesiology at the David Geffen School of Medicine, University of California, Los Angeles, USA.

Where – and how – do you focus your research?

After decades of research, there's still more knowledge being gained in terms of the neurobiology and pharmacology of the endocannabinoid system. At the same time, we know that people are using the cannabis plant in many different ways; for example, extracting and trying cannabinoids that we didn't even think about five years ago. There appear to be almost endless possibilities in connecting what we know from the animal literature about the pharmacology of cannabis-based compounds with what we know about how people are using the plant. And my area of expertise, in simple terms, is designing and running controlled human studies to try and integrate these two streams of information.

How did you find yourself heading up a cannabis research initiative?

Along my academic journey I became fascinated by how exogenous substances – especially drugs – interact chemically with the brain to elicit changes in mood and perspective. Unsurprisingly, my interest led to a deeper focus on psychoactive drugs, including opioids and cocaine. But it wasn't until around seven years later in 2007 that I started working with Meg Haney (who went on to become my mentor) and began exploring the effects of cannabis and cannabinoids.

Getting into the field at that time was particularly interesting because it felt so wide open – in fact, it was striking to me how little work had been done.

And what are today's big unanswered questions in cannabis research?

Cannabis is not one thing – it's a million different things, and people are not all the same. At a very fundamental level, those two aspects still need a great deal of unraveling. I know that's not one big question, and it's certainly not a single answer!

When it comes to medicinal cannabis, the science often lags behind perceptions and actual use of the drug – how do you feel about that as a scientist?

Good question. I think it puts us scientists in a tough spot. Public policy and public perceptions shift quickly – and the industry rapidly grows in new ways to capture the market. But, all too often, these views, trends, and decisions are not good indicators of where the science is at. While the rest of the globe is going through this real-life experiment, figuring out what's working (or not) for them, the science takes a long time to catch up. There may be a hot trend – CBG or delta-8-THC in the US right now – and we'll put in a grant, get funding a year later, start a randomized control trial, and begin collecting and analyzing data just as the next trend emerges… On the other hand – and despite the lag – it is at least gratifying to share robust data with people who would have not gained the evidence from any other source.

What research are you most proud of?

As a behavioral pharmacologist, what excites me most is when our results show a positive translation from preclinical models to humans, which doesn't happen all the time – far from it. And so it was very gratifying when we showed a strong sex-dependent effect of cannabis in humans – a wonderful reflection of what we observed in the animal literature. We also demonstrated the opioid sparing effect of THC in humans. And we're still digging into both of these areas.

What's the research funding landscape like – and who do you turn to for support?

Certainly, the cannabis industry is large and growing. But it's actually very difficult to get funding for scientific studies – in the US and across the globe. Fortunately, there's a very strong network of researchers who are either collaborating or sharing information, and that helps drive all this research forwards. There are excellent researchers across Europe, Australia (see page 12), and Israel, who have really pushed our field forward. For me, in the US, where we're dealing with a unique set of regulatory obstacles, developing close collaborations is really important. And that's why I still maintain close contact with Columbia University, where I stayed for about 13 years. Ryan Vandrey at Johns Hopkins has also been a tremendous source of collaborative energy. Closer to home, I work with Daniele Piomelli – a neuroscientist and scientific pioneer in the endocannabinoid system at the University of California, Irvine. There are many other influential people, groups, and institutions that have been instrumental in forwarding cannabis and cannabinoid science – it's an incredible network of talented scientists.

I will also say that the National Institutes of Health have been enormously helpful. Traditionally, they didn't fund therapeutic effects of cannabis and cannabinoids, but they have begun earmarking funds for this specific purpose. And they are genuinely interested in researchers finding success because they know how difficult it is.

Where would you like to see the field 10 years from now?

We're already on the path. We have ample data from survey reports, anecdotal reports, and observational studies – and they are important in helping us identify what patients are self reporting to be potentially effective. But we need to move on from those published data, integrating the findings into the well designed randomized control studies, where we can probe – in detail and with scientific rigor – specific cannabinoids and cannabis constituents (either isolated or combined) for specific indications. That's what we – and several other groups – are working towards.

Over the next 5–10 years, I think we're going to see a boom with respect to the data that will be available across different indications. And I'm really excited for that!

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