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Agnieszka Doll*

Making "Medical": How Psychedelics Are Becoming Legal in Canada

As legal restrictions loosen, psychedelic-assisted therapies are advancing at an unprecedented pace and scope in Canada and the US. Presented as a miracle cure for post-traumatic stress, depression, and other psychological disorders, psychedelics are being touted to treat post-pandemic mental health crises. In this paper, drawing on Science and Technology Studies, I ethnographically trace the ongoing process and practices involved in transforming illegal psychedelics into a regulated medicine in Canada, paying particular attention to regulatory pathways and the development of networks involved in psychedelic advocacy. Using these pathways as a methodological "sampling device," I map the main actors, their mutual relationships, and the resources mobilized to advocate the regulatory goals. By tracing this regulatory networking, I also demonstrate how domination and professionalization are being enacted alongside regulatory advocacy, raising questions about future equitable access to psychedelic-assisted therapies.

Alors que les restrictions légales s'assouplissent, les thérapies assistées par les psychédéliques progressent à un rythme et avec une ampleur sans précédent au Canada et aux États-Unis. Présentés comme un remède miracle contre le stress post-traumatique, la dépression et d'autres troubles psychologiques, les psychédéliques sont vantés pour traiter les crises de santé mentale post-pandémiques. Dans cet article, qui s'inspire des études sur la science et la technologie, je retrace de manière ethnographique le processus en cours et les pratiques impliquées dans la transformation des psychédéliques illégaux en médicaments réglementés au Canada, en accordant une attention particulière aux voies réglementaires et au développement des réseaux impliqués dans la défense des intérêts des psychédéliques. En utilisant ces voies comme un « dispositif d'échantillonnage » méthodologique, je cartographie les principaux acteurs, leurs relations mutuelles et les ressources mobilisées pour défendre les objectifs réglementaires. En retraçant ce réseau réglementaire, je démontre également comment la domination et la professionnalisation sont mises en œuvre parallèlement à la défense de la réglementation, ce qui soulève des questions quant à l'accès équitable futur aux thérapies assistées par les psychédéliques.

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Introduction

Medicines are made, and so is regulation. Yet, making them is not straightforward, especially regarding substances invested with historical baggage and cultural stigma, such as psychedelics. Still occupying a space of illegality in Canada, psychedelics are currently making a comeback as therapy and the desired commodity in addressing post-pandemic mental health crises. This article discusses recent initial efforts undertaken in Canada to transform psychedelics from substances prohibited by law into

legal medicine. It involves looking empirically at how the psychedelic regulatory regimes are being assembled, by whom, and with what effects. I focus specifically on so-called regulatory pathways through which such transformation has been undertaken. These pathways also serve as a methodological "sampling device" to map a network of actors and relations involved in transforming illegal psychedelics into regulated medicine in Canada.[1] The production of regulated medicine, as Science and Technology scholars Jeremy E. Greene and Sergio Sismondo note, "requires certain networks of relations in the first place, facilitates other, new formations, and can even obliviate longstanding traditions."[2] Uncovering and mapping them helps make visible various interests, strategies, and power relations invested in regulatory processes through which psychedelics are made medical to become legal for professionally-governed therapeutic use in Canada.

Psychedelics, also called hallucinogens, are a class of psychoactive substances (both botanical and synthetic) that cause, for example, dissociation and changes in cognitive perception. While botanical psychedelics have been used, for instance, in Indigenous communities for medicinal, therapeutic, and ceremonial purposes for centuries, the history of psychedelics in allopathic medicine can be traced back to the discovery of hallucinogenic substances in scientific laboratories.[3] The term *psychedelics* was coined in 1956 by the Canadian psychiatrist and researcher Humphrey Osmond who studied LSD and mescaline while corresponding with his American friend and writer, Aldous Huxley.[4] The term comes from a combination of two Greek words, *psyche* standing for mind and *dēloun* for making visible, revealing.[5] The most commonly

1. Jeremy A Greene & Sergio Sismondo "Introduction" in Sergio Sismondo & Jeremy Greene, eds, *The Pharmaceutical Studies Reader* (Newark: John Willey & Sons, 2015) at 5.
2. *Ibid*.
3. Beatriz Caiuby Labate & Clancy Cavnar, eds, *Plant Medicines, Healing and Psychedelic Science: Cultural Perspectives* (Cham: Springer, 2018); Yuria Celidwen et al, "Ethical Principles of Traditional Indigenous Medicine to Guide Western Psychedelic Research and Practice Indigenous Medicine to Guide Western Psychedelic Research and Practice" (2023) 18 The Lancet Regional Health – Americas, DOI: <10.1016/j.lana.2022.100410>; Ben Sessa, "The History of Psychedelics in Medicine" in Maxmillian von Heyden, Henrik Jungaberle & Tomislav Majić, eds, *Handbuch Psychoaktive Substanzen* (Berlin: Springer, 2016); Rafael Guimaraes dos Santos et al, "The Use of Classic Hallucinogens/Psychedelics in a Therapeutic Context: Healthcare Policy Opportunities and Challenges" (2021) 14 Risk Management & Healthcare Pol'y 901, DOI: <10.2147/rmhp.s300656>.
4. Erika Dyck, *Psychedelic Psychiatry: LSD on the Canadian Prairies* (Winnipeg: University of Manitoba Press, 2012) at 1-2 [Dyck, *Psychedelic Psychiatry*].
5. The term psychedelics may be resisted in some communities. Indigenous communities use the term plant medicines or "spirit medicine," or sacred medicines to refer to naturally occurring psychedelics, such as psilocybin or peyote, and foreground their historical roots in traditional practice; Labate & Canvar, *supra* note 3; Celidwen et al, *supra* note 3 at 3.

known psychedelics are Lysergic acid-diethylamide-25 in short LSD (also known as "acid"), 3-4 methylenedioxymethamphetamine in short MDMA ("ecstasy" or "Molly"), psilocybin ("magic mushrooms"), mescaline, N-dimethyltryptamine ("DMT"), Ibogaine, ayahuasca, peyote, and ketamine ("special K").[6] In Canada, most psychedelics are classified as controlled substances with no accepted medicinal use, except ketamine, approved as an anesthetic.[7] Regulated by the 1996 *Controlled Drug and Substance Act* [*CDSA*], psychedelics are categorized into schedules, according to which particular activities, such as sale, possession, and production, are permitted or restricted.[8] Under this legal regime, psychedelics generally are illegal in Canada unless authorized for medical, scientific, or industrial purposes.[9]

Despite being criminalized for decades, there is a renewed interest in psychedelics as potential treatments for mental health-related conditions. An increasing number of clinical trials testing the application of psychedelics for various mental health conditions have been initiated in the last two decades.[10] Since the beginning of the 2000s, prominent universities in Canada and abroad have established psychedelics research programs.[11] Also, the COVID-19 (COVID) pandemic and the

6. Psychedelics differ in their hallucinogenic/dissociative properties and pharmacological mechanisms. For example, based on their properties of altering the state of consciousness, psychedelics can be categorized into four groups: classical psychedelics (psilocybin, LSD, DMT), entactogens (MDMA), dissociative anesthetics (ketamine) and atypical hallucinogens (Ibogaine). See Albert Garcia-Romeu, Brennan Kersgaard & Peter Andy, "Clinical applications of hallucinogens: A review" (2016) 24 Experimental & Clinical Psychopharmacology 229, DOI: <10.1037/pha0000084>.

7. Government of Canada, "Controlled and Illegal Drugs*"* (last modified 07 February 2022), online: <canada.ca/en/health-canada/services/substance-use/controlled-illegal-drugs.html>.

8. *Controlled Drugs and Substances Act*, SC 1996, c 19 [*CDSA*]; These substances are categorized into Scheduled I to V to the CDSA. LSD, DMT, mescaline, and psilocybin fall under Schedule III of the CDSA and ketamine under Schedule I. Psychedelic substances are categorized under the category of restricted drugs of the CDSA and are regulated under Part J of the *Food and Drug Regulations,* CRC, c 870, online: <laws-lois.justice.gc.ca> [perma.cc/R57F-SC55]; The advantage of using schedules for listing and categorizing these substances is that such listing and categorizations can be changed administratively without the need to change the statutory provisions themselves.

9. Not all substances mentioned in the preceding paragraphs are illegal. For example, ibogaine is not illegal but is restricted in use to those with a prescription. For a more detailed explanation, see *CDSA, supra* note 8 s III.

10. National Library of Medicine, "ClinicalTrials.gov," online: <clinicaltrials.gov > [perma.cc/2XPX-SB7R].

11. Currently in Canada the University of British Columbia runs a psychedelics research lab, the University of Toronto runs an undergraduate course and research centre on psychedelics, and the University of Ottawa has its own centre for the study of psychedelics as well as launching in Fall 2023 the first Master's program in psychedelics in Canada as a development of its current micro-credential program (led by psychedelics researcher Monnica Williams), as do McMaster University and the University of Calgary. Vancouver Island University recently developed a post-graduate certificate for psychedelic-assisted therapy and the University of Wisconsin at Madison has developed a Master's program in psychedelic pharmaceuticals. Most recently, the University Health Network in Toronto has

reported spike in anxiety and depression among Canadians have further accentuated interest. During the first few months of the COVID pandemic, the rate of self-reported anxiety quadrupled from 5 per cent to 20 per cent, and self-reported depression doubled from 4 per cent to 10 per cent.[12] A poll conducted by Mental Health Research Canada in February 2021 demonstrates that "the proportion of Canadians who have reported their level of depression as high has increased by 70 per cent since the height of COVID's first wave."[13] Suicidal ideation is also on the rise across Canadian provinces. For example, between April 2021 and August 2021, the percentage of Canadians thinking about suicide increased from 12 per cent to 14 per cent, suggesting that one out of seven Canadians thinks about suicide. Psychedelics are seen as substances that can address the mental health impact of the COVID pandemic.[14]

The regulation of psychedelics, however, is a complicated matter. In many current societies, psychedelics occupy a precarious status where their meaning ranges from cure to poison, from a legal remedy to "illegal succour and pleasure."[15] The boundaries between legal and illegal in the context of psychedelics can be blurred and their legal status constructed differently. At one point, psychedelics can be both illegal and legal. For example, while currently prohibited, psychedelics can be accessed legally for scientific and research purposes. One "modern" way to mitigate such precarious and ambivalent status of substances that are "seen to sit on the knife-edge or risk and benefit" is through medical prescription and converting them into legal medicine.[16]

Drawing on insights from Science and Technology Studies (STS) and data from digital ethnography, this paper portrays the landscape of an early

established the Psychedelics Psychotherapy Research Centre. In the United States, psychedelics are studied at the University of Stanford, Harvard's Medical School, Penn State University, UC San Diego and Harbour UCLA, John Hopkins, Columbia, Purdue, and the University of Alabama. In the UK, psychedelics are studied at the University of Bristol, Kings' College London, and Imperial College London. This list is by no means exhaustive.

12. This data included the first months of the pandemic until April 2020. See Mental Health Research Canada, *How COVID-19 is Impacting Canadians* (Mental Health Research Canada, 2020), online: <static1.squarespace.com> [perma.cc/EP7E-386P].

13. Mental Health Research Canada, *Mental Health During Covid-19 Outbreak: Poll # 5 of 13 in Series* (Mental Health Research Canada, 2021) at 3, online: <static1.squarespace.com> [perma.cc/4JMA-NFE7].

14. Mental Health Research Canada "National Poll on Canadian Mental Health: 17 Studies in an Ongoing Series" (2021) at Poll 6 & 8, online: <mhrc.ca> [perma.cc/F2EN-AYLK]; Elena Argento et al, "Psychedelics-Assisted Psychotherapy After COVID-19: The Therapeutics Uses of Psilocybin and MDMA for Pandemic-Related Mental Health Problems" (2021) 12 Frontiers in Psychiatry 716593, DOI: <10.3389/fpsyt.2021.716593>.

15. Greene & Sismondo, *supra* note 1 at 5.

16. *Ibid*.

regulatory effort undertaken in Canada to transform psychedelics into a regulated medicine.[17] By focusing on the early regulatory undertaking, it attends to "one specific moment" (from mid-2020 till early 2022) in a longer process of psychedelics "becoming" a regulated medicine that is still underway. As Western "psychedelic medicine" is constantly reinventing and rectifying itself, zeroing in on specific moments allows us to concretely map assemblages of actors, legal instruments, tools, and strategies through which new pharmaceutical developments are enacted and how actors, objects and networks fluctuate, change, and transform over time. The shifts from "being to becoming, from legal objects…to events"[18] requires departing from equating legalization with the moment when law or regulation is passed to seeing it as a dynamic and multifaceted process that involves an assemblage of numerous actors, relations, and interests, some of which will shift but other will stabilize over time.[19] According to socio-legal and Science and Technology Studies scholars Máiréad Enright and Emilie Cloatre "the becoming" is a "process in which the interactions of particular agents, across a range of political sites, transform the social nature of the object regulated by law, in turn changing the law itself: a process that combines spectacular moments and the slower pace of everydayness."[20] Mapping such networks, their formation, mobilization, and changes, involves uncovering and describing how actors connect to "form a web of activity, and how they are thus changed, or translated, in becoming part of a network."[21] Through such exercise "networks of power can be revealed, which may be producing and reproducing issues of inequalities."[22] Some of the inequalities in the context of psychedelics may pertain to equitable access to professionally delivered psychedelic-assisted therapies when they gain market approval given the already known

17. Emilie Cloatre, "Law and ANT (and its Kin): Possibilities, Challenges, and Ways Forward" (2018) 45:4 J Law and Society 646, DOI: <doi.org/10.1111/jols.12133>; Bruno Latour, *The Making of Law: An Ethnography of the Conseil D'Etat* (Cambridge: Polity, 2010); Kate Seear, *Law, Drugs and the Making of Addiction* (London: Routledge, 2020); Magdalena Goralska, "Anthropology from Home: Advice on Digital Ethnography for the Pandemic Times" (2020) 27 Anthropology in Action 1, DOI: <10.3167/aia.2020.270105>; Deana Simonetto, "Expanding our Methodological Toolbox: The "Place" on Twitter in the Ethnographic Endeavour" (2016) Qualitative Sociology Review 12:1 at 98, DOI: <10.18778/1733-8077.12.1.05>.

18. Niels van Dijk, "The Life and Deaths of a Dispute," in Kyle McGee, ed, *Latour and the Passage of Law* (Edinburgh: Edinburgh University Press, 2015) at 166.

19. Máiréad Enright & Emilie Cloatre, "Transformative illegality: How condoms 'became legal' in Ireland, 1991–1993" (2018) 26 Feminist Leg Studies 261, DOI: <10.1007/s10691-018-9392-1>.

20. *Ibid* at 261.

21. Jennifer Scoles, "Researching 'Messy Objects': How can Boundary Objects Strengthen the Analytical Pursuit of an Actor-Network Theory Study?" (2018) 40:3 Studies in Continuing Education at 277, DOI: <10.1080/0158037x.2018.1456416>.

22. *Ibid.*

significant costs of these therapies, or to the exclusion of certain groups of therapists or healers from partaking in a highly regulated psychedelic-assisted therapies market.

This article reports on data collected through ethnographic fieldwork between July 2020–February 2022. During that time, I conducted 20 qualitative interviews with advocates, researchers, therapists, regulators, and lobbyists. I also engaged in an extended digital ethnography following actors and their activities on social media, following changes on institutional websites, press releases, social media tweets, etc. I participated in online network meetings, regulatory and advocacy seminars, and various webinars organized by these actors as well as by Health Canada, the main regulator of pharmaceuticals in Canada. I also closely read legal and regulatory texts, regulatory proposals, biomedical research, and parliamentary debates on legal changes to psychedelics in Canada. Through these data, I mapped not only specific activities but also the regulatory network involved in advocating and enacting regulatory pathways for medicinal access to psychedelics in Canada, specifically identifying who the main actors were, their mutual relationship, types of connections, interests, and their advocacy and regulatory strategies.

My data collection was primarily limited to drug regulation at the federal level, as this was the level where research and development of novel interventions were initiated in Canada.[23] Also, as judicial decisions have a limited impact on Canadian pharmaceutical regulation the investigation and discussion in this article focused on statutory regimes in the form of regulatory pathways.[24] Furthermore, because changes to intellectual property regulations were not part of the early legal and regulatory assemblages mobilized towards regulatory changes to the legal status of psychedelics in Canada legal matters of intellectual property rights, (e.g. patentable extraction techniques, new molecules, or even protocols for psychedelic therapies) remain outside the scope of my discussion in this article. This does not mean that companies have not filed patent applications related to psychedelics to prepare for commercializing medicinal psychedelics and psychedelic-assisted therapies in Canada.

23. Despite this focus it is important to note the influence that provinces (as well as cities) have had on drug regulation in the past as well as the present. Currently, provinces and territories determine which drugs to pay for out of the public purse after HC approves drugs for sale. This dynamic creates a constant, at times fraught, interplay between the two levels of government and the standards and processes they utilize to approve and assess drugs. See Coleen M Flood & Patrick Dyke, "The Data Divide: Managing the Misalignment in Canada's Evidentiary Requirements for Drug Regulation and Funding" (2012) 45:2 UBC L Rev 283, DOI: <10.2139/ssrn.1997448>.

24. Matthew Herder, *Drug Regulation* [unpublished, manuscript on file with the author].

In the first section of the article, I provide an overview of the Western scientific, social, and legal histories of psychedelics, emphasizing the interplay between medical science, research and regulation in Canada. Moving from the 1950s until the 2010s, I speak to the emergence of psychedelic psychiatry in Canada, the installment of prohibitionist policies, the "War on Drugs," and changes to drug policies in the new millennium. While this section provides a historical background, it also demonstrates the close entanglement between researchers, scientists, and regulators in developing medicinal psychedelics in the past. Furthermore it shows how some regulatory pathways that are being advocated for legal access to medicinal psychedelics were used in the past for other controlled substances. In the second section, drawing on my ethnographic and legal desktop research, I describe in detail the four pathways (and the associated legal provisions) around which (between 2020 and 2022) actors working towards the regulatory medicalization of psychedelics in Canada centered their efforts. These pathways include: (1) Clinical Market Entry (CME) pathway with clinical trials; (2) section 56(1) of the Controlled Drugs and Substances Act (CDSA); (3) Special Access Program (SAP); and (4) Medical Assistance in Dying (MAiD) regulations. While discussing them, I map the network of actors involved in advocating each pathway, the relationships between them, and how those connections allowed them to share scientific and regulatory knowledge and resources to increase the effectiveness of their advocacy.

Even though the article makes modest claims of a descriptive nature, mapping the institutional landscape of early regulatory developments of psychedelics in Canada is worth undertaking. It can provide a springboard for further analysis of changes to (as well as stabilization of) this landscape, strategies, and interests. Based on an empirically grounded illustration of micro-level activities and practices involved in psychedelic advocacy in Canada, the 2020–2022 landscape of regulatory advocacy in Canada emerged to be dynamic and multilayered, yet dominated by a few key organizations leading research, development, and regulatory advocacy in Canada. At the same time, the psychedelic regulatory landscape seems to be constantly in flux, with multiple new actors, some that emerged out of those pre-existing organizations, and others were newly formed, of whom some were attracted by the "massive market potential of psychedelics."[25] As networks are dynamic entities; alliances between organizations also shift alongside social, cultural, economic, and political changes as well

25. PSYCH, *The Psychedelics as Medicine Report 2021* (Blossom, 2021) at 13, online: <psych.global> [perma.cc/NW3S-6PUZ] [*Report 2021*].

as ones in organizations' internal politics or leadership.[26] This speaks to the fact that the process of "becoming" and making psychedelics legal in Canada is dynamic and complex, with multiple dimensions pursued through various legal pathways, united by the goal of professionalizing and commercializing access to psychedelics as regulated medicine.

When it comes to the four regulatory pathways, often seen in legal and psychedelic literature as distinct fields of efforts towards medical access to psychedelics, in practice, they are entangled in multiple and significant ways. For example, scientific evidence produced via clinical trials has been used to legitimize regulatory advocacy for access through other pathways. Opening one pathway can legitimize and amplify evidence generated or claims made within the context of another one. In this sense, contemporary pathways are co-evolving, mutually shaping, and amplifying each other, increasing the potential for strategic regulatory interventions of involved actors.[27]

Lastly, the data can help counter claims put forward by some of the actors discussed in this article regarding their commitment to include Indigenous knowledge keepers and leaders in developing regulatory solutions.[28] Like other critical scholars, I also observed the lack of inclusion of Indigenous knowers as actors in the development of legal pathways for medicinal psychedelics.[29] In fact, scholars of Indigenous and post-colonial thought, such as Keith Williams, consider the current hype surrounding research and development of psychedelics as a resemblance of the colonial past because of its extractivist qualities.[30] Likewise, the subsumption of psychedelic-assisted therapies under a purely biomedical framework with

26. Bryn William-Jones & Janice E Graham, "Actor-Network Theory: A Tool to Support Ethical Analysis of Commercial Genetic Testing" (2003) 22:3 New Genetics and Society 271, DOI: <10.1080/1463677032000147225>.

27. For an interesting discussion of the mutual entanglement of psychedelics imaginaries pertaining to the future legal landscape in the US, see Claudia Schwartz-Plaschg, "Socio-psychedelic Imaginaries: Envisioning and Building Legal Psychedelics Worlds in the United States," (2022) 10:10 European J Future Research, DOI: <10.1186/s40309-022-00199-2>.

28. MAPS Canada, Newsletter, "MAPS Vision for Diversity" (18 June 2020), online: <us14.campaign-archive.com> [perma.cc/ZBB9-LE4G]; Psychedelic Association of Canada, "Inclusion, Diversity, and social justice" (2022) online: <psychedelicassociation.net> [perma.cc/KQY4-5EDM].

29. See Keith Williams et al, "Indigenous Philosophies and the "Psychedelic Renaissance""(2022) 33:2 Anthropology of Consciousness 506, DOI: <10.1111/anoc.12161>; Celidwen et al, *supra* note 3; Neşe Devenot, Trey Conner, & Richard Doyle, "Dark Side of the Shroom: Erasing Indigenous and Counterculture Wisdoms with Psychedelic Capitalism, and the Open Source Alternative" (2022) 33:2 Anthropology of Consciousness 476, DOI: <10.1111/anoc.12154>; Jamilarh R. George, "The Psychedelic Renaissance and the Limitations of a White-dominant Medical Framework: A Call for Indigenous and Ethnic Minority Inclusion" (2020) 4:1 J Psychedelic Studies, DOI: <10.1556/2054.2019.015>.

30. Williams et al, *supra* note 29.

the presumed superiority of western medical knowledge and its neoliberal individualistic approach is another aspect of colonial legacy.[31]

I. *Psychedelics' regulatory past: The nexus of science, medicine, and law*

1. *The emergence of psychedelic psychiatry in Canada*

While for centuries, many societies and communities, including Indigenous communities worldwide, have been using various hallucinogenic substances for medicinal, therapeutic and ceremonial purposes, the history of psychedelics in allopathic medicine can be backtracked to hallucinogenic substances. This includes mescaline, LSD, and MDMA in scientific laboratories (See Table 1), which were of interest to psychiatrists studying and treating mental disorders or other medical conditions.[32] Canada became an important hub for clinical research and therapeutic practice. The early days of western psychedelics research can be traced to the 1930s and 1940s. In 1938 Albert Hofmann, a Swiss biochemist who worked at Sandoz Pharmaceutical Laboratories and synthesized LSD, found LSD's hallucination potential when he incidentally drank it with water.[33] A few years earlier, DMT had been first synthesized by Richard Manske, working for the National Research Council Canada, and two decades earlier, in 1919, mescaline by German chemist Ernst Späth. During the 50s, interest in LSD and mescaline spread across clinical, biomedical, and other professional communities in Europe and North America.[34]

In the 1950s and 1960s, the province of Saskatchewan became a hub for clinical trials and experimentation with LSD and mescaline.[35] These experiments were intended to broaden psychiatric knowledge, better understand the causes and manifestations of schizophrenia, and apply psychedelics to treat alcohol addiction. Humphrey Osmond was a

31. Celidwen et al, *supra* note 3 at 5; Joseph Dumit & Emilia Sanabria, "Set, Setting, and Clinical Trials: Colonial Technologies and Psychedelics" in Maja Hojer Bruun, Wahlberg Ayo, Douglas-Jones Rachel, Hasse Catherine, Hoeyer Klaus, Kristensen Dorothe B & Winthereik Brit R, eds, *Palgrave Handbook of the Anthropology of Technology* (Singapore: Palgrave Macmillan, 2022) at 291–308; Alex K Gearin & Neşe Devenot,"Psychedelic Medicalization, Public Discourses, and the Morality of Ego Dissolution" (2021) 24:6 Intl J of Cultural Studies 917, DOI: <10.1177/13678779211019424>.

32. Sessa, *supra* note 3; Dyck, *Psychedelic Psychiatry*, *supra* note 4.

33. Dyck, *Psychedelic Psychiatry*, *supra* note 4 at 13; Lucas Richert, *Strange Trips: Science, Culture, and the Regulation of Drugs* (Montreal & Kingston: McGill-Queen's University Press, 2018) at 8.

34. For example, between 1951 to 1961, the number of scientific articles published on LSD increased from a hundred to over a thousand. See Dyck, Psychedelic Psychiatry, *supra* note 4 at 15.

35. Erika Dyck, "Prairie Psychedelia: A Sympathetic look at a Canadian Mental Hospital and its Controversial Past" (2016) 24:3 Literary Rev of Can 1 at 24-25 [Dyck, "Prairie Psychedelia"]; Kay Parley, *Inside the Mental: Silence, Stigma, Psychiatry and LSD* (Regina: University of Regina Press, 2016).

crucial figure in that field, a British psychiatrist interested in psychosis who moved to Canada in 1951 to take up the clinical director position at the Saskatchewan Mental Hospital in Weyburn. Along with other local researchers, Osmond developed a research program that investigated the biological and biochemical basis of schizophrenia, which included experiments with LSD for health professionals to simulate the experiences of psychosis of their patients.[36] They also developed a form of psychedelic therapy that used a dose of LSD within a framework of intensive psychotherapy (that serves as a template for current psychedelic-assisted therapies).[37] At that time, access to LSD was legal and simple to obtain for scientific purposes from the Canadian branch in Quebec of Sandoz Pharmaceutical Company, the sole manufacturer of the drug.[38]

Table 1. Historical and Current Trajectory of Medical and Legal Activities Related to Psychedelics

Date	Event
1908	Canada passes *Opium and Narcotic Drug Act*
1912	MDMA is synthesized and patented
1919	Mescaline is synthesized
1920	Canada passes *Food and Drug Act* (F&DA)
1931	DMT is synthesized
1938	LSD is synthesized in Sandoz Laboratories
1943	Albert Hoffman experiences LSD's hallucination potential
1947	First LSD studies on humans
1951	Humphrey Osmond moves to Canada to take a post at Mental Hospital in Weyburn
1960s	Changes to *Food and Drug Act* regarding evaluation of safety and effectiveness
1961	Canada passes *Narcotic Control Act*
1961	Schedules of "Controlled Drugs" are added to F&DA
1962	Schedules "Restricted Drugs" added to F&DA

36. With these experiments, Osmond was interested in developing a novel theory of schizophrenia grounded in hormonal imbalance; In part, these promising avenues of research helped convince regulators that LSD was worth pursuing as a clinical substance. See Richert, supra *note* 33 at 84.

37. Matthew Oram, *The Trials of Psychedelic Therapy: LSD Psychotherapy in America* (Baltimore: Johns Hopkins University Press, 2018) at 3.

38. To obtain LSD, researchers needed to go through Sandoz' review of their application and study proposal. Later the manufacturing and distribution of LSD in Canada were undertaken by the Connaught Medical Laboratories in Willowdale, Ontario. See Dyck, *Psychedelic Psychiatry*, *supra* note 4 at 172.

1962	The order-in-council places LSD on a restricted substances list under the F&DA
1963	Canadian federal government introduces additional surveillance on researchers accessing LSD
1963	Sandoz temporarily suspends the distribution of LSD
1966	Canadian Senate and House of Commons consider LSD's placement on the official list of narcotics
1969	A change to F&DA that added Section IV
1969	LSD with other two substances (DET and STP) is included under the F&DA's as a restricted substance
1969	The Le Dain Commission is established
1972	Recommendation of the Le Dain Commission
1974	Psilocybin is included under F&DA as a controlled substance
1986	MDMA is included under F&DA as a restricted substance
1986	Canadian Prime Minister Brian Mulroney declares "War on Drugs"
1996	Canada passes *Controlled Drugs and Substances Act*
2001	Enactment of a medical cannabis program called *Medical Marijuana Access Regulation*
2004	Ketamine becomes a controlled substance
2007	Canadian Prime Minister Stephan Harper introduces *National Anti-Drug Strategy*
2013	Changes to Special Access Program excluding psychedelic compounds
2014	First clinical trial of psychedelic therapies starts in Canada as a pilot phase 2 trial
2016	Liberal government *Canadian Drugs & Substances Strategy*
2017	HC approves ayahuasca use for some religious groups for a limited time
2017	Ibogaine enters the Prescription Drug List
2018	Canada passes *Cannabis Act*
2020	First clinical trials on psychedelic therapies sponsored by a Canadian company and conducted in Canada
2020 August	For the first time a patient is granted access to psilocybin under s. 56(1) of the *CDSA*
2021 March	The first group of therapists is granted access to psilocybin under s. 56(1) for training purposes
January 5, 2022	Changes to Special Access Program that revert the exclusion of psychedelic compounds

By the early 1960s, things began changing for psychedelic researchers in Canada, making their work more difficult. A few factors, including scientific, medical, cultural, and economic ones, contributed to this change. First, after the tragedy of thalidomide, a marketed drug that led to severe congenital disabilities in children in Canada and elsewhere, governments started to rethink the pre-market assessment of new drugs. During the 1960s and 70s randomized controlled trials (RCTs) were introduced to ensure adequate and proper testing for the safety of new drugs and "were gaining traction as the preferred experimental design for determining the safety and effectiveness of an intervention or drug."[39] Yet, psychedelics misfit with randomized clinical trials contributed to the "death" of psychedelics research in decades to come, as researchers could not prove, as required by standards of RCTs, the efficacy of the substances or therapies in treating certain medical conditions.[40] Second, there was also an ongoing a broader radical transformation in psychiatric knowledge-making since the 1950s.[41] It included the incorporation of biostatistics (adopted from epidemiology) and psychometrics (adopted from clinical psychology) with the effect of changing clinical practice and altering psychiatric science in a novel way.[42]

Third, the circulation of drugs in society, particularly psychedelics, "created challenges for medical researchers faced with the growing reputation that these substances were merely agents of abuse" and the stigma that was subsequently attached to psychedelics.[43] The moral panic that began in the United States due to the widespread recreational use of drugs, including LSD, created the narrative for understanding psychedelics and carried material effects for psychedelics researchers.[44] For instance, an influx of LSD to the market caused practical difficulties with running clinical trials with this substance; scientists had difficulties controlling the use of LSD by their trial participants outside of the research context. This, in turn, posed problems with the validity of psychedelic trials.[45] Furthermore, Sandoz, the provider of LSD for medical research, temporarily suspended the production of LSD, worrying about its reputation due to substances

39. Matthew Herder, "Pharmaceutical Regulation in Canada" in Joanna Erdman, Vanessa Gruben & Erin Nelsen, eds, *Canadian Health Law and Policy* (Toronto: LexisNexis, 2017) at 187.
40. For a fascinating discussion of these challenges, see Oram, *supra* note 37.
41. Allan Young, *The Harmony of Illusions: Inventing Post-Traumatic Stress Disorder* (Princeton: Princeton University Press 1995) at 7 and 102-107.
42. *Ibid.*
43. Richert, *supra* note 33 at 88.
44. PJ Giffen, Shirley Endicott & Sylvia Lambert, *Panic and Indifference: The Politics of Canada's Drug Laws: A Study in the Sociology of Law* (Ottawa, Canada: Canadian Centre on Substance Abuse, 1991) at 91; Richert, *supra* note 33 at 84.
45. Richert, *supra* note 33 at 84.

sold under the label of LSD. As a result, obtaining LSD for clinical research became substantially more difficult. Nonetheless, because of the promising results of clinical trials and anticipated near-breakthroughs, drug regulators, at least for some time, were willing to work closely with scientists to develop ways to facilitate the continuation of this promising research (despite the politicization of these substances).[46] Nonetheless, issues of financial sustainability of health centres where experiments were conducted in a therapeutic context played in the diminish of clinical trials on psychedelics during that era.[47]

Amongst this challenging context, further regulatory and legal changes that would affect the progress of research on the medicinal use of psychedelics were already on the horizon. In fact, psychedelics, specifically LSD, were to be an object of regulatory scrutiny and prohibition debates that occurred with intensity in the next decade in Canada and abroad.

2. *Towards the prohibition of psychedelics and the "War on Drugs"*

In 1961 Canada passed the *Narcotic Control Act*, which was one the most punitive drug laws in the Western Hemisphere.[48] Although psychedelics were not included among narcotics and therefore clinical trials with these substances could continue, there undergoing attempts to restrict access to them but for medical purposes.[49] Should LSD and potentially other psychedelics be placed on that narcotics list, this would remove the possibility of continuing psychedelics research.[50] Yet, with time LSD "became synonymous with counterculture activities, hedonism, and drug abuse," a portrait widespread by public media.[51] In that context, in 1962, in debates over the thalidomide tragedy, politicians and drug regulators again

46. Dyck, *Psychedelic Psychiatry*, *supra* note 4.

47. Greg Marchildon & Erika Dyck, "The Psychedelic World of Hollywood Hospital" (13 January 2022), online (podcast): <champlainsociety.utpjournals.press/podcast/wty/the-psychedelic-world-of-hollywood-hospital>; In Canada, trials were conducted at the Champlain Society in Canada, and for trials held in the USA, see Oram, *supra* note 37.

48. *An Act to Provide for the Control of Narcotic Drugs*, SC 1961, c 35; Susan Boyd, *Heroin: An Illustrated History* (Fernwood Publishing: Halifax, 2022) at 121; The new law emerged in the context of Canada adopting the UN Single Convention of Narcotic Drugs and the need to ensure the consistency between international and domestic laws; Tara L Bruno & Rick Csiernik, *The Drug Paradox: An Introduction to the Sociology of Psychoactive Substances in Canada* (Canadian Scholars: Toronto, 2018) at 22.

49. Senate, *Report of the Senate of Special Committee on Illegal Drugs* (September 2002), online: <sencanada.ca> [perma.cc/HSK7-B4FQ]; Dyck, "'Just say know': Criminalizing LSD and the politics of psychedelic expertise" in Edgar-Andre Montigny, ed, *The Real Dope: Social, Legal, and Historical Perspectives on the Regulation of Drugs in Canada* (Toronto: University of Toronto Press, 2011) 169 [Dyck, "Just Say Know"].

50. Dyck, *Psychedelic Psychiatry*, *supra* note 4.

51. Erika Dyck, "LSD: A New Treatment Emerging from the Past" (2015) 187:14 Can Medical Assoc J 1079, DOI: <doi.org/10.1503/cmaj.141358>.

considered LSD for inclusion on the list of prohibited substances. While this attempt was unsuccessful, the 1962 order-in-council placed LSD on a list of controlled drugs under the *Food and Drug Act* (F&DA). This made drug possession legal, but the sale and purchase a criminal offence, except for research purposes.[52] Additionally, in 1963, the government introduced new measures on researchers accessing LSD, requiring them to apply through the federal Minister of Health rather than through Sandoz.[53] Formal permission from the federal Minister of Health was now required to obtain LSD from Sandoz.[54] Again in 1966, LSD appeared in the Canadian Senate and House of Commons debate for placement on the official list of narcotics.[55] Eventually, in 1968, LSD, with another three substances, was included under amendments to the F&DA as drugs enumerated in Schedule J which meant that clinical experiments could continue while the use was criminalized. Still the penalties were less severe penalties than it would have been under the *Narcotic Control Act* (see Table 2).[56] Shortly after, psilocybin was added to the list of controlled substances in 1974.[57] The next psychedelic, MDMA, became illegal in 1986. With increasing difficulty with securing drugs for research purposes, specifically LSD, plus the negative public sentiments towards drugs and associated regulatory changes, by the mid-1960s, research units were slowly abandoning work in that area.[58] In 1969, the Le Dain Commission (officially called the Canadian Commission of Inquiry into the Non-Medical Use of Drugs) was established to assess Canadian drug law, and its recommendations released in 1972 suggested removing harsh penalties for drug possession and personal use. These recommendations were not implemented, and prohibition continued. Furthermore, in the mid-80s, then-Prime Minister Brian Mulroney declared war on drugs following a similar move of United States President Ronald Regan.[59]

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52. *Food and Drugs Act*, RSC 1985, c F-27 [*F&DA*]; Dyck, *Psychedelic Psychiatry*, *supra* note 4. In the debate over thalidomide, politicians and drug regulators also considered including LSD on the list of prohibited substances, even restricting its medical and research usage.
53. Dyck, "Just Say Know," *supra* note 49 at 169-196; Dyck, *Psychedelic Psychiatry*, *ibid* at 168.
54. Dyck, *Psychedelic Psychiatry*, *ibid.*.
55. *Ibid.*
56. That legal change came in the form of an amendment to the F&DA that created Part IV to govern substances listed in Schedule J. See A Ross Chapman, "Recent Changes in Canadian Food and Drug Legislation" (1970) 25:7 Food Drug Cosm LJ 338.
57. Psychedelic Law, "Psilocybin," online (website): <Psychedeliclaw.ca> [https://perma.cc/5S8P-TQ7G].
58. Dyck, "Prairie Psychedelia," *supra* note 35 at 24.
59. Akwasi Owusu-Bempah & Alex Luscombe, "Race, Cannabis, and the Canadian War on Drugs: An Examination of Cannabis Arrest Data by Race in Five Cities" (2021) 91 Intl J of Drug Policy 1, DOI: <10.1016/j.drugpo.2020.102937>; Indeed, the dramatic rise in the prosecution for possession and trafficking of marijuana between 1966-67 helped motivate the "Le Dain Commission." See

Table 2. Comparison of some drug offences under various statutes

Offences	*Narcotic Control Act*	*Food and Drug Act*	
	Narcotics e.g., heroin, cocaine, cannabis.	**Controlled drugs** (Schedule G) e.g., amphetamine, methamphetamine.	**Restricted drugs** (Schedule J) e.g., LSD, MDMA, MDA.
possession	Section 3 Maximum penalty is 7 years imprisonment on indictment, 6 months of imprisonment or a $1000 fine, or both on summary conviction. The max. penalty for the subsequent offence is 1 year imprisonment or $2000 or both.		Section 47 Maximum penalty is imprisonment for no more than 3 years, or a fine not exceeding $5000, or both on indictment. No more than 6 months of imprisonment or a fine not exceeding $1000, or both on summary conviction; for any subsequent offence is imprisonment for a term not exceeding one year or a fine not exceeding $2000, or both.
possession for the purpose of trafficking and trafficking	Section 4 Maximum penalty is imprisonment for life.	Section 39 Maximum penalty is imprisonment of no more than 10 years on indictment or 18 months on summary conviction.	Section 48 Maximum penalty is imprisonment of no more than 10 years on indictment or 18 months on summary conviction.

Despite all of this, the federal drug law remained unchanged until the mid-1990s when in 1996, the *Controlled Drugs and Substances Act* (CDSA) was enacted in response to the 1988 UN Convention Against Illicit Trafficking in Narcotics and Psychotropic Substances, to which Canada became a signatory.[60] The act repealed the *Narcotic Control Act* (1961–1996) and parts III and IV of the *Food and Drugs Act.* Under the CDSA, MDMA, psilocybin, and other hallucinogens were classified in Schedule I and III drugs. Schedule I included the most addictive, such as MDMA and ketamine, and Schedule III ones that were less. These drugs' sale, production, and possession were prohibited unless otherwise

Commission of Inquiry into the Non-Medical Use of Drugs, *Final Report of the Commission of Inquiry into the Non-Medical Use of Drugs* (Ottawa: Commission of Inquiry into the Non-Medical Use of Drugs, 1973), online: <publications.gc.ca> [perma.cc/S42R-WXUA]; Bruno & Csiernik, *supra* note 48 at 24.

60. Owusu-Bempah & Luscombe, *supra* note 59; *CDSA, supra* note 8 c 19.

authorized for research or clinical purposes.[61] Even currently, when undertaking research with substances regulated by the CDSA, a researcher must apply to the Controlled Substances and Cannabis Branch of Health Canada's Controlled Substances Directorate for an exemption from the provisions of the CDSA (I address this issue in detail in Section II of this article).

Because of the government's punitive stance that pervaded from the mid-1970s until the beginning of the 2000s and the many legal hoops researchers had to navigate to access restricted substances for scientific purposes, legal medical and scientific research on psychedelics during that time was restricted. Yet, in a psychedelic underground, compounds were produced, and psychedelic therapies continued to be delivered, thereby contributing to scientific and therapeutic knowledge on healing properties of psychedelics and delivery methods.[62] Also, Indigenous communities continued practicing their traditional medicine with sacred plants, a tradition spanning centuries. Both endeavors continued to enrich our understanding and laid the ground for contemporary Western psychedelic science.[63]

3. *Psychedelics and Canadian drug policy in the new millennium*

While Canada's punitive control of cannabis and other illicit drugs into the New Millennium continued, some significant changes paved the path for the current activities pertaining to psychedelic advocacy. In 2001, the federal government enacted medical cannabis called the *Medical Marijuana Access Regulation* (MMAR) after the *Parker* case.[64] The significance of this change for regulating and accessing psychedelics is in a trajectory of applying section 56(1) of the CDSA (detailed in section II of the article) as a statutory exemption from prosecution for the possession of cannabis prescribed by a physician.[65] Furthermore, in 2003 the Ontario Superior Court ruled that the MMAR was unconstitutional as it did not provide legal means for patient access to prescribed cannabis, ultimately suspending its decision to give Health Canada time to remedy the situation.[66] Yet,

61. *R v Parker (T),* 135 OAC 1.
62. Danielle Giffort, *Acid revival: The psychedelic renaissance and the quest for medical legitimacy* (Minneapolis: University of Minnesota Press, 2020); Microdose, "From Underground LSD Chemist to Mainstream Psychedelic Medicine: PsyGen Labs Peter Van Der Heyden Opens Up at The Mushroom Conference" (20 November 2020), online: <microdose.buzz> [perma.cc/C7JM-KBNM]; Devenot, Conner & Doyle, *supra* note 29.
63. Devenot, Conner & Doyle, *supra* note 29; Williams et al, *supra* note 29.
64. *Parker*, *supra* note 61.
65. Chelsea Cox, "The Canadian Cannabis Act legalizes and regulates recreational cannabis use in 2018" 122:3 (2018) Health Policy at 205-209, DOI:<10.1016/j.healthpol.2018.01.009>.
66. *Hitzig v Canada*, 2003 CanLII 3451 (ON SC).

those rulings did not make federal governments generally more relaxed. To the contrary, the conservative Premier Stephen Harper announced a new National Anti-Drug Strategy a year after becoming Canada's Prime Minister. This strategy emphasized law enforcement over treatment and prevention, promising to introduce mandatory minimum sentencing for cannabis and other drug-related offences under the CDSA.[67]

Canadian heroin-assisted therapy (HAT) clinical trials for opiate treatment are another legal and regulatory development that can be seen as paving a trajectory for accessing psychedelics as an experimental therapy. Specifically, the 2005 North American Opiate Medication Initiative (NAOMI) and 2011 Study to Assess Longer-term Opioid Medication Effectiveness (SALOME). In the context of the trials, precisely after their ending, the provisions of the Special Access Program (SAP) were used to access experimental therapies (including those involving illegal drugs) for medical purposes for individuals where other treatment options were unavailable or ineffective. Contrary to international recommendations for addiction trials, participants in these trials were not offered continued treatment at the end of either trial and were forced to discontinue treatment. To remedy this, harm reduction advocates, along with some doctors, developed a strategy of submitting SAP applications for patients who would benefit from heroin-assisted therapy and Health Canada (HC) approved a number of patients for receiving injectable heroin for three months after exiting the trial.[68] However, a month later, in October 2013, in light of the National Anti-Drug Strategy, the federal government announced the changes to the federal regulations pertaining to SAP, making heroin, along with products containing heroin, unauthorized forms of cocaine as well as LSD, ecstasy, "magic" mushrooms, and "bath salts," no longer available through SAP.[69] Related, constitutional challenge was undergoing when the liberal government came into power, and respectively in 2016 HC announced a proposal for a regulatory change to consider applications under the SAP to facilitate the treatment of chronic relapsing opioid dependence with heroin and later reinstalled such access.[70] Yet, this

67. During this time *Safe Streets and Communities Act* was passed; Owusu-Bempah & Luscombe, *supra* note 59; *Safe Streets and Communities Act*, SC 2012, c 1, online: <canlii.ca> [perma.cc/B3HF-HQKW].

68. Safe Streets and Communities Act, *supra* note 67.

69. Government of Canada, "Changes to Special Access Program" (October 2013), online: <canada.ca/en/news/archive/2013/10/changes-special-access-program-sap-.html>.

70. Health Canada, Press Release, "Health Canada to propose a regulatory change to enable consideration of an application under the Special Access Programme to Facilitate Treatment of Chronic Relapsing Opioid Dependence" (13 May 2016), online: <canada.ca/en/health-canada/news/2016/05/health-canada-to-propose-regulatory-change-to-enable-consideration-of-applications-

proposed regulatory change did not include substances other than heroin, such as psychedelics.

Furthemore, HC started to approve exemptions for accessing psychedelics, specifically ayahuasca, for religious purposes (under section 56(1) exemption) for a number of religious groups for a limited time.[71] In 2017, The Eclectic Centre for the Universal Flowing Light (Ceu do Montreal) and Beneficient Spiritist Centre Uniao do Vegetal received HC's exemption after a decade of unsuccessful attempts.[72] In 2018, HC approved three more religious groups (The Ceu da Divina Luz do Montreal, Eglesia Santo Daime Ceu do Vale de Vida in Val-David, Que., The Ceu de Toronto) for an exemption to import ayahuasca for ceremonial purposes.[73]

Lastly, with the passage of the *Cannabis Act* in June 2018, which included changes to the CDSA and other acts, the federal government ended the specific prohibition on cannabis, providing legal access to cannabis and regulating its production, distribution, and sale.[74] These legal and regulatory changes, along with other factors, are important for understanding the emerging Canada's leadership (among US and a few other countries) in transforming psychedelics from illegal drugs into legal medicine.[75]

Alongside these legal and regulatory changes to drug policies in Canada, there was also a renewed scientific interest in the therapeutic potential of psychedelics. The first clinical trials involving psychedelics started to be undertaken in Europe and North America in the 90s. They surfaced on the wave of dissatisfaction related to the lack of progress with new pharmacological treatments for psychiatric disorders. As a prominent psychedelic researchers, David Nutt and others, writes, "revisit[ing] drugs that were once used but fell out of use" was seen as a "way out" of that stagnation caused by disinterested major pharmaceutical companies.[76] Likewise, there has been a general disappointment with antidepressants and other psychotropic drugs.[77]

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under-the-special-access-programme-to-facilitate-treatment-of-chronic-relapsing-opioid-dependence.html>.

71. Cillian O'Brien, "Health Canada Allows More Religious Groups to Import Psychedelic Ayahuasca," *CTV News* (8 May 2019), online: <ctvnews.ca> [perma.cc/X3P4-TJPY].

72. *Ibid.*

73. *Ibid.*

74. *An Act Respecting Cannabis and to Amend the Controlled Drugs and Substances Act, the Criminal Code and other Acts,* SC 2018, c 16.

75. Cision, "Why Canada is Becoming a Hub for Psychedelics Research and Development," (17 March 2021), online: <prnewswire.com> [perma.cc/H4WM-FJPY].

76. David Nutt, David Erritzoe & Robin Carhart-Harris, "Psychedelic Psychiatry's Brave New World" (2020) 18:1 Cell 24, DOI: <10.1016/j.cell.2020.03.020>.

77. Bruce Levine, "From Peer Support to Psychedelics: Psychiatry's Co-Optation & De-

This renewed interest in psychedelics is often called the psychedelic renaissance.[78] Research groups in Europe and North America began investigating "the neurobiological effects of psychedelics as well as their clinical safety and efficacy profile for the treatment of mental health conditions such as post-traumatic stress disorder (PTSD), depression, addiction, or end-of-life anxiety."[79] In Canada, for example, in September 2014 a Phase 2 pilot study for treatment of PTSD with the MDMA-assisted therapy began in Vancouver, Canada with an aim of testing the dosage to be used for Phase 2 and 3 clinical trials for the US-based sponsor, Multidisciplinary Association of Psychedelics Studies (MAPS), a leading organization in psychedelic research.[80] Early pilot studies gave Canadian therapists experience delivering MDMA-assisted psychotherapy for PTSD as a preparation for their involvement for next stages of clinical trials. Later in 2019, Canada became one of the two non-US based clinical trials sites for MAPS' trial on effectiveness of MDMA-assisted therapies.[81] Those trials put Canada on the international map of important research hubs for psychedelics research and development.

In the following section, I will continue the discussion of the clinical trial regulatory pathway as well as outline other recent developments in the transformation of psychedelics in Canada through which psychedelics are becoming "medical" to become legal in Canada. These new developments came into being through various efforts of actors involved in psychedelics advocacy in Canada, which I also explore accordingly.

II. *New dawn for psychedelics? Networking regulatory changes*

In the past and present, Canada has emerged as one of the leaders in developing what Erika Dyck calls psychedelic psychiatry.[82] In addition to being a site of clinical trials involving psychedelics, since mid-2020, various opportunities for legal access to psychedelics for medicinal purposes have opened up in Canada. For example, in August 2020, Canada's Minister of Health granted several individual exceptions for

Radicalization" (23 March 2023), online (blog): <brucelevine.net online> [perma.cc/CV4Q-ENWX]; Nicholas Langlitz, "Psychedelic Innovations and the Crisis of Pharmacology" (2022) BioSocieties, DOI: <10.1057/s41292-022-00294-4>.

78. The term "psychedelics renaissance" is attributed to Ben Sessa. See *supra* note 3.

79. Claudia Schwartz-Plaschg, "Socio-Psychedelic Imaginaries: Envisioning and Building Legal Psychedelic Worlds in the United States" (2022) 10:1 European J Future Research 1 at 2, DOI:<10.1186/s40309-022-00199-2>.

80. Multidisciplinary Association for Psychedelic Studies (MAPS), "Protocol MP-4" (20 June 2014) at 6, online: <maps.org> [perma.cc/F6RY-NBKC] [MAPS].

81. National Library of Medicine, "Long-Term Safety and Effectiveness of MDMA-Assisted Therapy for PTSD," online: <clinicaltrials.gov> [perma.cc/KJ7T-PCZV].

82. Dyck, *Psychedelic Psychiatry, supra* note 4.

access to psilocybin for palliative care patients. One and a half years later, HC, the key regulator of pharmaceutical and biologic therapies in Canada, decided to implement revisions to the SAP, making it available, under conditions specified by law, for accessing psychedelics and psychedelic-assisted treatments despite still having an investigational therapy status.

In this section, drawing on my ethnographic fieldwork, I map and discuss four regulatory pathways through which advocacy regulatory efforts have been streamlined in Canada between mid-2020 and early 2022. The first pathway is the Clinical Market Entry (CME), the second involves exemptions under section 56(1) of the CDSA, the third–is access to psychedelics under SAP, and the fourth is access to psychedelics under the provisions for medical assistance in dying (MAiD). The first pathway involves the conduct of clinical trials to prove the safety and efficacy of therapies for future commercial roll-out as marketed drug products. The remaining three pathways can be labelled as compassionate access pathways because they are oriented towards providing early or temporary access to treatment or relief from grievous suffering for persons with severe or irremediable health conditions, including treatments that might not have received regulatory approval. Within that context, a patient can access "therapeutics use of unauthorized drugs outside of clinical trials."[83]

For analytical clarity, I discuss each pathway separately, although many intersections exist between them. In real life, these pathways are entangled, and actors are connected through various nodes and pathways creating a dynamic assemblage of psychedelic regulatory advocacy in Canada. First, I will discuss the governing legal framework pertaining to each pathway and changes to them if such occured. Then, I map and present key actors playing instrumental roles within each pathway. A few central actors emerged in the early days of regulatory undertakings. The list includes the Multidisciplinary Association for Psychedelic Studies US (MAPS) and its subsidiary MAPS Public Benefit Corporation (MAPS PBC), Multidisciplinary Association for Psychedelic Studies Canada (MAPS Canada), Numinus Wellness, Inc (Numinus), TheraPsil, the Canadian Psychedelic Association (currently called Psychedelic Association of Canada), and Field Trip Wellness, Inc.

83. Jan Borysowski & Andrzej Gorski, "Compassionate Use of Unauthorized Drugs: Legal Regulations and Ethical Challenges" (2019) 65 European J Internal Medicine 12 at 12, DOI: <10.1016/j.ejim.2019.04.008>.

1. *Market entry pathway*

a. *Regulatory provisions for clinical market entry pathway (research & development)*

Accordingly, the clinical market entry pathway has emerged as the most prominent pathway that current organizations in the field are undertaking to legalize access to psychedelics in Canada. The conduct of clinical trials and the process of regulatory approval of drugs is governed by the provisions of the F&DA and overseen by HC.[84] According to F&DA, a clinical trial is "a study, involving a human subject, for the purpose of discovering or verifying the effects of a drug, a device or a food for special dietary purpose."[85] HC emphasizes that "clinical trials remain the best option to request access to restricted drugs (or any other unapproved drugs) and to generate scientific evidence" on the safety and efficacy of a given treatment.[86] Based on the evidence provided as a part of the application package submitted by a drug sponsor (the applicant), HC authorizes pharmaceutics (as well as other health products and devices) for their safety and efficacy so they can be sold as medicine in Canada.[87] Without such authorization, products cannot be commercialized.

To conduct clinical trials in Canada, scientists must receive HC authorization. The Office of Clinical Trials is responsible for authorizing applications for clinical trials on pharmaceutical drug products. Additionally, for trials using certain controlled drug substances (such as psilocybin, MDMA, etc), the qualified investigator, meaning a practitioner affiliated with universities or private industry ("QI"), must also receive an exemption under section 56(1) of the CDSA or authorization under Part J of the Food and Drug Regulations (FDR).[88] The Minister can specifically exempt a QI, for research purposes, from the prohibition to undertake activities related to controlled substances and precursor chemicals, such as the purchase, possession, and use of controlled substances. Once issued, the exemption or authorization will allow the QI to purchase, possess and administer the controlled substance to human subjects for their research. After the application is received, HC issues a "No-Objection-

84. Health Canada, *Guidance Document for Clinical Trial Sponsors: Clinical Trial Applications* (Ottawa, 2013), online: <canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/clinical-trials/clinical-trial-sponsors-applications.html>.

85. *F&DA, supra* note 52 at 2.

86. Health Canada, Notice: Clarifications Regarding Access to Restricted Drugs through the Special Access Program (SAP) (23 July 2021), online: <canada.ca/en/health-canada/services/drugs-health-products/special-access/notice-clarifications-regarding-restricted-drugs-program.html>.

87. See *F&DA, supra* note 52 at s 2.

88. *CDSA, supra* note 8.

Letter" (NOL) to the applicant within 30 days of receiving the complete application; granted, no major issues are identified during the review of the study protocol. The applicant may also receive questions from HC about the protocol or consent form and must respond to these questions within two days.

b. *Assembling market entry pathway through clinical trials*

At the moment of writing this article in 2022, neither a single psychedelic compound, nor an adjunct to psychedelic therapy has yet been authorized in Canada for commercialization as a newly approved drug. Clinical trials on DMT and MDMA have been ongoing since the 90s, with a significant increase in their numbers in the last two decades in Europe and the US. In Canada, the first clinical trials for psychedelics started in 2014, with trials for the prescription use of MDMA-assisted psychotherapy in patients with chronic and treatment-resistant post-traumatic stress disorder sponsored by the MAPS as an open-label pilot trial.[89] In August 2017, the US FDA granted MAPS a "Breakthrough Therapy Designation" for its MDMA-assisted psychotherapy for PTSD.[90] These designations indicate that psychedelics may substantially improve existing treatments for mental illness. As of 2018, MAPS launched another open-label trial (Phase 2) in Canada to assess safety of MDMA for patients with least severe PTSD. Vancouver and Montreal were among the clinical trial sites.[91] In 2019 the British Columbia Centre on Substance Use (BCCSU) ran the trial in Vancouver which assisted MAPS in the conduct of the first part of phase 3 of randomized double-blinded clinical trial sought to test MDMA-assisted psychotherapy in Canadian residents with chronic treatment-resistant PTSD.[92] The most advanced, randomized, blinded clinical trials on psychedelics of MAPS on MDMA entered their phases II and III in 2017 and 2019, respectively. Since then, MAPS has conducted pivotal and confrimatory phases III of that clinical trial and launched additional trials on the application of MDMA for treating PTSD of differing severities with clinical trial sites in Canada.[93] Initially these trials were organized

89. MAPS, *supra* note 80.

90. MAPS, Press Release, "FDA grants Breakthrough Designation for MDAM-Assisted Therapy for PTSD, Agrees on Special Protocol Assessment for Phase 3 Trials" (26 August 2017), online: <maps.org> [perma.cc/Q6WQ-RKAD].

91. National Library of Medicine, "Study of Safety and Effects of MDMA-Assisted Psychotherapy for Treatment of PTSD (Canada)," online: <clinicaltrials.gov> [perma.cc/PL3E-SVC4].

92. Kerry Banks, "The Canadian Revival of Psychedelic Drug Research," *University Affairs* (14 June 2019), online: <universityaffairs.ca> [perma.cc/SJW2-24FX]

93. MAPS, *supra* note 80 at 6; National Library of Medicine, "Randomized Double-blind, Controlled of MDMA-assisted Psychotherapy in 12 Subjects With PTSD," online: <clinicaltrials.gov> [perma.cc/3F4U-355C].

and coordinated by MAPS CANADA, and later by MAPS' long-term collaborator from Toronto, Dr Anne Wagner, who was previously involved in MAPS' clinical trials in the United States as a therapist.[94] Wagner later established Remedy Institute with an intention of holding the next MAPS trials (as well as those sponsored by Remedy). More recently, Numinus became another clinical site for MAPS' trials, whose chief medical officer, Dr Evan Wood was a former Executive Director at the BCCSU and a professor at the University of British Columbia.[95]

MAPS is a non-profit research and educational organization established in 1986 by its current Executive Director, Rick Doblin.[96] Doblin is a Harvard-trained psychologist who studied with Dr Stanislav Grof, considered one of the founders of Western psychedelic science and known for his early studies of LSD and its potential for psychiatry. Following the path of his mentor and building on his psychological training, Doblin committed to MAPS' effort to legalize psychedelics, such as MDMA, for prescription use in the therapeutic professional context. This orientation heavily relies on the medicalization of psychedelics as adjuncts for psychotherapies and the demonstration of their pharmacological effects on diagnosed medical conditions, such as PTSD.[97] To assist MAPS in running clinical trials in Canada, fundraising and promotion, Mark Haden (in collaboration with Doblin) established MAPS Canada in 2011 and registered it as a charitable organization.[98] While being Executive Director of MAPS Canada, Haden also became associated with BCCSU, where MAPS clinical trials were run.

According to the HC database, as of February 2022, 12 studies have received authorization to conduct clinical trials on psychedelics, excluding ketamine (a significant increase from the 7 studies authorized as of June 2021).[99] Since then, HC approved more clinical trials. At the

94. Wagner is also an adjunct professor at the Metropolitan University in Toronto, Canada. See The Conversation, "Anne Wagner," online: <theconversation.com> [perma.cc/QFL4-RDWX].

95. Aya Gonzalez, "Vancouver-based Numinus Wellness Hires Addiction Expert Dr. Evan Wood as Chief Medical Officer," *Numinus* (21 May 2020), online: <numinus.com> [perma.cc/YU4H-2ME7]; Numinus Wellness, "Dr. Evan Wood, Recognized leader in the Field of Substance Use Research and Treatment, Joins Numinus as Chief Medical Officer," *Cision News* (21 May 2020), online: <newswire.ca> [perma.cc/6AUJ-P56C].

96. Darek Dawda, "MDMA-Assisted Therapy 2020 with Rick Doblin—ENHANCED THERAPY PODCAST" (24 November 2020), online (Podcast): <enhancedtherapy.ca> [perma.cc/6J95-8PHQ]. See also, MAPS, "Rick Doblin," online (website):<maps.org> [perma.cc/5NC9-DZEY].

97. *Ibid.*

98. MAPS USA as an organization located in the US could not legally raise funds in Canada for its MDMA clinical trials. My interview with an official from MAPS Canada, 23 September 2020.

99. "Health Canada's Clinical Trials 202 Session" (Delivered by HC and attended as part of fieldwork research, 14 July 2021) [unpublished] ["Health Canada Clinical Trials"].

beginning of April 2022, there were seven trials on psilocybin and seven on MDMA, including those completed, ongoing and pending, that involve human subjects.[100] As of December 2021–April 2022, most clinical trials with MDMA (6 out of 7) in Canada were sponsored by MAPS.[101] The remaining one has been conducted by Remedy Institute.[102] With time, Numinus, closely connected with MAPS and MAPS Canada, started to play an increasingly significant role as a trial partner for MAPS. Numinus is a Canadian company founded in 2019 and has Numinus Biosciences as its subsidiary, which is publicly traded. While in the early years, the BCCSU served as the site for MAPS's clinical trials, as Dr Wood joined Numinus Wellness in 2020, clinical trials for MAPS were being transferred to Numinus' facilities. This move coincided with Mark Haden's, who organized and coordinated clinical trials for MAPS, departure from MAPS Canada for Psygen, a psychedelic manufacturing company, in early 2021.[103]

The significance of the CME pathway for the transformation of psychedelic substances into medicine in Canada lies not only in the fact that HC recommends clinical trials as "the most appropriate and effective way to advance research with unapproved drugs while protecting the best interests of patients."[104] CME and clinical trials conducted within it has also provided other actors involved in opening advocating for the use of s. 56 and SAP with important data on safety and efficacy of psychedelic and psychedelic assisted therapies.

2. *Section 56(1) of CDSA*

a. *Regulatory provisions*

Another pathway for accessing psychedelics in the medical domain in Canada has been through the use of section 56(1) of the CDSA.[105] In subsection 1 a), it was mentioned that section 56(1) is used to exempt researchers conducting clinical trials with controlled substances from criminal responsibility. The application of section 56(1) is not restricted to the research context. The federal Minister of Health can exempt any persons or class of persons and any controlled substance on any terms and conditions the Minister considers necessary for medical, scientific

100. "Health Canada Clinical Trials," *supra* note 99.
101. *Ibid.*
102. Dawda, *supra* note 96.
103. Fieldnotes, 6 December 2020.
104. Health Canada, Information Session: Clinical Trials and the Special Access Program, 24 March 2022 [Pdf on file with the author].
105. *CDSA*, *supra* note 8.

and research purposes. Accordingly, the application of section 56(1) can proceed in the following ways. The Minister can exempt any person, such as persons with a terminal illness, class of persons or any controlled substance on any terms and conditions the Minister considers necessary for medical purposes. Upon receiving the exemption, a person may possess, administer, or transport controlled substances without criminal liability, depending on the prescribed terms and conditions. There is no prescribed timeline for the Minister's decision on applications submitted under section 56(1) and each application submitted by patients is assessed individually.

This section also allows for classes of individuals to be grounded exemptions. For example, section 56(1) was used to exempt from prosecution persons in charge of a hospital and or a pharmacist who supplied controlled substances to a community health facility, patients, practitioners and pharmacists prescribing and providing controlled substances in Canada during the coronavirus pandemic, or pharmacists, practitioners, persons in charge of a hospital and licensed dealers for the provision and destruction of unserviceable stock and post-consumer returns. In the context of the COVID opioid crisis, the federal department of health issued a short-term section 56(1) exemption authorizing practitioners to verbally prescribe controlled substances and pharmacists to prescribe, sell, or provide such substances in limited circumstances, as well as allowing for the transfer of authorized prescriptions for controlled substances. These exemptions also enable individuals to deliver controlled substances to those in COVID related isolation.[106] In the context of psychedelic advocacy, such class exemptions became essential for training purposes to allow a group exemption of psychedelic therapists to access controlled substances and consume them during training sessions.

b. *Assembling access to psychedelic via section 56(1)*

The assemblage of this pathway came through efforts of actors involved in psychedelics advocacy in Canada, with a notable role of a non-profit coalition from British Columbia, TheraPsil, and built on "precedents" that opened section 56 for access to cannabis. TheraPsil was established in 2019 by Bruce Tobin, a psychologist from Nanaimo. TheraPsil is "a non-profit coalition of healthcare professionals, patients, and advocates

106. Government of Canada, "Subsection 56(1) Class Exemption for the Person in Charge of a Hospital and/or a Pharmacist who Supplies Controlled Substances to a Community Health Facility" (9 January 2019), online: <canada.ca/en/health-canada/services/health-concerns/controlled-substances-precursor-chemicals/policy-regulations/policy-documents/subsection-56-class-exemption-person-in-charge-hospital-pharmacist-controlled-substances-community-health-facility.html>.

dedicated to obtaining legal access to psilocybin for Canadians in medical need."[107] Its objectives are public education, professional education, research, and promoting legal access to psilocybin.[108] TheraPsil was the first organization to help individual patients with more immediate, direct access to psychedelics.[109] In June 2020, TheraPsil started to assist patients with submitting applications under section 56(1). In August first patients were granted legal access to psilocybin and by the end of December 2021, a total of 47 palliative care patients with a terminal diagnosis or in remission from a life-threatening diagnosis (e.g., cancer survivors) had been approved for such exemption (with the support of TheraPsil).[110] The wait time in obtaining such decisions were significant as patients had to wait several months.[111] The advocates feared the precarity of access to psychedelics and psychedelic-assisted therapies under section 56(1), as it took years of advocacy to obtain.[112] The successful access to section 56(1) has been associated with the current Minister, Patty Hajdu, who has advocated for harm reduction strategies in her previous work. One of the concerns was the upcoming elections in Fall 2021 and the fear that the next Minister may change their approach to section 56(1).[113] In that context, the initiative for including access to psychedelic therapies via SAP and for end-of-life palliative care under MAiD emerged, which I discuss in more detail in subsections three and four.

Psychedelic advocates also made use of CDSA section 56(1) to apply for an exemption of healthcare professionals from the CDSA provisions to allow them to use psychedelics within the training context. By 19 February 2022, healthcare professionals, with the help of TheraPsil, had been authorized by the Minister to possess and use psilocybin for professional training in psilocybin therapy. These approved professionals include psychologists, psychiatrists, clinical counsellors, social workers and nurses.[114] Over a year later, as of January 2022, another group of 86

107. TheraPsil, "About TheraPsil" (2022), online: <therapsil.ca> [perma.cc/ZAF4-5JMX].
108. TheraPsil, "TheraPsil's 4 Pillar Mission" (2022), online: <therapsil.ca> [perma.cc/TP2R-4SCY].
109. TheraPsil, "Psilocybin Therapy for End-of-Life Distress—First Legal Treatment in Canada, Webinar" (21 August 2020), online (webinar): <therapsil.ca> [perma.cc/M9GA-Z52W].
110. TheraPsil, "3 Canadians Approved for Psilocybin Therapy to Treat Depression & Anxiety" (14 December 2021), online: <therapsil.ca> [perma.cc/LG4A-PHCZ].
111. *Ibid.*
112. Bethany Lindsay, "4 Dying Canadians Wait to Hear if They'll Be Allowed to Try Magic Mushrooms for Their Anguish" *CBC News* (19 July 2020), online: <cbc.ca> [perma.cc/2MBU-UD2C].
113. Fieldnotes from a meeting, 24 July 2022.
114. TheraPsil,"17 Canadian Healthcare Professionals Approved to Use Psilocybin for Professional Training" (8 December 2021), online: <therapsil.ca> [perma.cc/CHF7-RKHB] [Can Health Professionals Approved].

healthcare practitioners enrolled in TheraPsil's psilocybin therapy training program and submitted section 56(1) exemption requests.[115] However, at the beginning of February 2022, the Minister notified them of "an intent to refuse" their exemptions and provided 14 days for responses to the notification before final decisions were made. More than a hundred therapists were waiting for CDSA section 56(1) exemptions to undertake their training in psilocybin therapies provided by TheraPsil. As this paper was finalized in February of 2022, TheraPsil was considering applying for judicial review of each decision and filing "necessary mandamus applications to compel decisions for all outstanding Section 56(1) exemptions."[116]

TheraPsil was the first Canadian organization to provide training in psychedelic therapies for therapists in Canada. Before that, in the US MAPS was the first to design and organize training for therapists for psychedelic therapies. MAPS has been training for specific protocols for which they conducted clinical trials on MDMA and has the most extensive training capacity until now.[117] MAPS training sessions are conducted in the US and during the pandemic, were partially via Zoom. While MAPS conducted the training, MAPS Canada was responsible for recruiting Canadian candidates who met the criteria for enrollment for MAPS training. During one of MAPS Canada's information sessions for therapists, I observed that the demand for such training exceeded the number of spots provided for those training sessions. Two training sessions were offered by MAPS in 2021. However, limited capacity has made access to MAPS training very competitive for Canadians. According to my research, participants who completed MAPS training in the Fall 2021 session, among 500 participants, only 30 were professionals from Canada.[118] The cost was $5 000 USD per person, and an additional few thousand dollars to cover MAPS supervision during the final clinical component of the training.[119] Yet, because the market was unsaturated, both organizations, MAPS and TheraPsil, rather than competing, supported each other's effort to establish access to psychedelic-assisted therapy training in Canada by sharing institutional knowledge and resources.

115. TheraPsil,"Letters of Support Psilocybin Access for Training Purposes" (3 February 2022), online: <therapsil.ca> [perma.cc/P3JA-B92K].
116. Microdose, "Non-Profit TheraPsil Raising Funds to Fight for Psilocybin Access" (3 May 2022), online: <microdose.buzz> [perma.cc/GE6V-FYZW].
117. Fieldnotes, October 2021.
118. Interview, 4 February 2022.
119. *Ibid.*

3. *Special Access Program*

a. *Regulatory provisions*

As of 5 January 2022, access to psychedelics as therapeutics and psychedelics therapies are available under HC's SAP after the restrictions of the 2013 amendment were lifted. Compassionate access allows early access to potentially beneficial investigational therapies for people facing a serious or life-threatening condition for whom currently available treatments have not worked and cannot participate in clinical trials.

Requirements of the SAP are outlined in *Food and Drug Regulations* ("F&DA Regulations"), sections C.08.010 and C.08.011.[120] The amendments that came into force in 2013 state that all products containing heroin, unauthorized forms of cocaine, and other drugs, including LSD, MDMA, psilocybin, and bath salts, were ineligible for consideration under the SAP.[121] Under the SAP, medical practitioners in Canada can request access to drugs that are generally unavailable for sale in Canada.[122] For that certain conjunct conditions are imposed, including the need for severe or life-threatening conditions and the failure of conventional therapies, unsuitability, or unavailability.[123] Under the SAP, normal requirements for market authorization are overridden, including pre-market testing and evidence from clinical trials and market approval as a precondition for access to drugs or therapists.

Requests for access under the SAP are made by practitioners and submitted to the Minister of Health. The Minister may issue such a letter of authorization if the practitioner provides information on the name of the drug, details of the medical emergency, the quality of the drug, as well as on its use, safety, and efficacy,[124] if the new drug has been previously authorized under the SAP for the same medical emergency, has the authorization (without conditions) of the EMA (European Medicines Agency) or the US Food and Drug Administration for the same use,[125] and

120. *Food and Drug Regulations*, CRC, c 870 (2023) [*F&DA Regs*].
121. Government of Canada, News Release, "Heroin and Other Dangerous Drugs Are Banned from Health Canada's Special Access Programme—Government of Canada Puts Safety and Security of Canadians First and Focuses on Treatment and Recovery" (3 October 2013), online: <https://www.canada.ca/en/news/archive/2013/10/heroin-other-dangerous-drugs-are-banned-from-health-canada-special-access-programme-government-canada-puts-safety-security-canadians-first-focuses-treatment-recovery.html>.
122. Health Canada, *Special Access Program for Drugs: Guidance Document for Industry and Practitioners* (Ottawa, 2022) at 7, online: <https://www.canada.ca/en/health-canada/services/drugs-health-products/special-access/drugs/guidance.html> [*SAP Guidance*].
123. *Ibid; F&D Regs*, *supra* note 120 s C.08.010(1).
124. *F&DA Regs*, *supra* note 120 s C.08.010(1)(a)(i).
125. *Ibid*, sC.08.010(2)(a)-(c).

its identification number has not been cancelled, the practitioner does not have to provide information pertaining to the use, safety, and efficacy of the new drug.[126]

In addition to the above, the requesting practitioner needs to provide the name and the civic address of the person (either a practitioner or a pharmacist) to whom the new drug is to be shipped, as well as any other information the Minister may deem relevant to deciding whether to issue the letter of authorization.[127] Furthermore, the practitioner must agree to report the results of the use of the drug in the medical emergency to its manufacturer and the Minister, including any adverse reactions.[128] A physician can only request a specific amount of the drug for a specific patient or possibly a few individualized patients of the same physician, for a maximum of six months of treatment.[129] This requires that physicians reapply in the case of longer treatments. The practitioner assumes liability for all quantities of the drug received.[130] Upon meeting all the required conditions, a letter of authorization will be issued by the Minister stating the name of the practitioner to whom the new drug might be sold, the name and the civil address of the persons to whom the new drug may be shipped; the medical emergency in respect of which the new drug may be sold and the quality of this new drug.[131] Decisions are made promptly and should occur within 24 hours.[132] The cost of the drug is determined by the manufacturer, who also "may impose conditions on the use of the drug prior to the issuance of the authorization to sell to a practitioner."[133] Such conditions can even include providing a protocol for drug use. Notably, HC cannot require that manufacturers, in fact, sell the drug to the practitioner who received SAP authorization.[134]

b. *Assembling the Special Access Program*

This pathway differs significantly from that under section 56(1) CDSA, as it has imposed a timeline for ministerial decision-making and is restricted

126. *Ibid*, s C.01.014.6(2)(b)-(c).
127. *Ibid*, *s* C.08.010(1)(1) (iv-v).
128. *Ibid,* s C.08.010(1)(b)(i).
129. SAP Guidance*, supra* note 122; Adam R Houston et al, "Reforming Canada's Special Access Programme (SAP) to improve access to off-patent essential medicine" (2018) 3:2 Official J of the Assoc of Medical Microbiology and Infectious Disease Can 100 at 103, DOI: <10.3138/jammi.2018.01.04>.
130. *SAP Guidance*, *supra* note 122 at 18.
131. *F&DA Regs*, *supra* note 120 s C.08.010(2)(a-d).
132. Health Canada, "Health Canada' Special Access Programs: Request a Drug" (2 February 2022), online: <https://www.canada.ca/en/health-canada/services/drugs-health-products/special-access/drugs.html>.
133. *Ibid; SAP Guidance*, *supra* note 122 at 22.
134. Interview, *supra* note 118.

to a therapeutic context. Psychedelic advocates in Canada perceived accessing psychedelics for patients in critical conditions via SAP as a better and less "political" option than the section 56(1) exemption as they believed that it has more predefined criteria. The local physician also makes the initial assessment, not the Minister or bureaucrats, making this procedure more predictable in terms of timeframe.[135]

The SAP in Canada was initially enacted in 1992 as the Emergency Drug Release Program.[136] In 2013, HC excluded from SAP all products containing heroin, unauthorized forms of cocaine and other drugs considered. Alongside heroin, LSD, ecstasy, "magic" mushrooms, and "bath salts" were excluded from SAP.[137] Those exclusions were justified in reference to the National Anti-Drug Strategy.[138] Due to those regulatory changes, those restricted drugs became ineligible for emergency authorization for physicians treating patients under their care. Yet, according to HC, even before 2013, SAP was not used to access psychedelics or psychedelic-assisted treatment.[139] This statement however needs to be contextualized in light that the most advanced clinical trials on psychedelics, such as those conducted by MAPS on MDMA, did not enter phase III until 2019 and for SAP product's safety and efficacy needs to be demonstrated.

Before becoming available in Canada, access to investigational MDMA therapies became available in the USA through its Expanded Access Program (EAP), and in Israel.[140] While the EAP in the U.S. differs from SAP in Canada, MAPS advocacy in that direction carries implications

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135. Fieldwork notes, *supra* note 117.

136. Canadian Neuroendocrine Tumor Society, "Toronto-2008-Health Canada's Special Access Program – Ian Mackay, Health Canada" (21 July 2016), online (video): <https://www.youtube.com/watch?v=Mpf55WwE4Us>.

137. *Regulations Amending Certain Regulations Concerning Prescription Drugs (Repeal of Schedule F to the Food and Drug Regulations)*, CRC (2013), online: <https://canadagazette.gc.ca> [perma.cc/8MUR-5FX2].

138. Government of Canada, "Heroin and Other Dangerous Drugs Are Banned from Health Canada's Special Access Programme-Government of Canada Puts Safety and Security of Canadian First and Focuses on Treatment and Recovery" (3 October 2013), online: <https://www.canada.ca/en/news/archive/2013/10/heroin-other-dangerous-drugs-are-banned-from-health-canada-special-access-programme-government-canada-puts-safety-security-canadians-first-focuses-treatment-recovery.html>.

139. Fieldwork notes, 13 May 2022, "Clinical Trials and Special Access Program webinar."

140. MAPS, "Expanded Access Program for MDMA Health Canada—Assisted Therapies for Patients with Treatment-Resistant PTSD," online: <mapspublicbenefit.com/our-research/expanded-access-program/>; MAPS, Press Release, "FDA Agrees to Expanded Access Program for MDMA-Assisted Therapy for PTSD (17 January 2021), online: <maps.org> [perma.cc/3YJS-9KUT] [MAPS, "Expanded Access"]; MAPS Multidisciplinary Association for Psychedelic Studies, Press Release, "Expanded Access Protocol Submitted to the FDA" (2 January 2019), online:<maps.org> [perma.cc/F2G7-JPFH]; Report 2021, *supra* note 25.

for advocating for compassionate access in other jurisdictions, in which MAPS was involved as a sponsor of clinical trials, with an example of Israel and Canada. In January 2019, MAPS Public Benefit Corporation, a subsidiary of MAPS, sent a formal protocol to the U.S. FDA for the EAP for MDMA-assisted psychotherapy for post-traumatic stress disorder (PTSD). In December 2019, MAPS received U.S. FDA authorization to establish an expanded access program for 50 patients. As of January 2022, MAPS continued preparation for the EAP launch, inspecting and accrediting sites chosen for the program delivery.[141] In this way, MAPS paved a path for its Canadian partner organizations to advocate for similar compassionate access for patients in Canada.

In Canada, the steps towards advocating with HC to revisit the limitation of SAP for accessing psychedelics began before August 2020. Although Numinus is often credited for opening the door to psychedelics therapies in Canada via SAP, the initiative came, in fact, from the Director of MAPS Canada, Haden, who prepared a request to HC to consider revisions to the SAP.[142] On 11 April 2019, MAPS Canada, in collaboration with the Canadian Drug Policy Coalition and British Columbia Centre on Substance Use, officially submitted a letter to HC requesting a change to the F&D Act.[143] In this letter, they referred to the US Expanded Access program to gain approval in the US and the phase II clinical trials examining the effectiveness of MDMA-assisted psychotherapy for PTSD clinical trials pursued by MAPS Canada and the BCCSU. In their letter, they advocated explicitly for a professionally supervised access to MDMA and psilocybin-assisted psychotherapies "provided by trained and licenced professionals in a closely supervised setting."[144]

The work of pushing for regulatory changes to SAP was continued later by Numinus with Dr Wood, who was previously involved in challenging Canada's drug policy through his work on launching a constitutional challenge related to heroin access, leading that effort.[145] Numinus Wellness was established in early 2020 due to a Reverse Take-Over Transaction between Rojo Resources Ltd with Salvation Botanicals, a Canadian cannabis testing and processing company.[146] On 20 November 2020, a

141. MAPS, "Expanded Access," *supra* note 140.
142. Interview with MAPS, May 2021; Copy of the 11 April 2019 letter (send via email to HC), on file with the author [Copy of the Letter].
143. *Ibid.*
144. *Ibid.*
145. Dan Small, "Fighting Addiction's Dead Row: British Columbia Supreme Court Justice Ian Pitfield Shows a Measure of Legal Courage" (2008) 5:1 Harm Reduction J 31, DOI: <doi.org/10.1186/1477-7517-5-31>.
146. "Rojo Resources Ltd. Announces the Conditional Approval of Reverse Take-Over Transaction

letter requesting revisions to SAP was submitted by Numinus to HC.[147] In the letter, Numinus specifically recommended that the HC's SAP be revised to "allow for consideration of applications for access to MDMA- and psilocybin-assisted psychotherapies via the Special Access Program mechanism."[148] It also recommended delineating the context and protocol for administering the drug by trained psychotherapists, a model of therapy tested in clinical trials by MAPS.[149] Numinus worked with HC to advocate for evidence-based revisions to the SAP regulation, building on the results of clinical trials conducted under the CME pathway. In December 2020, HC announced *Proposal to restore potential access through the SAP* and assigned two months for public consultation.[150] During that time, MAPS Canada and other psychedelic advocates utilized their webinars, listservs, and connections with professional communities to mobilize expression of support for HC's proposal. MAPS Canada collected around 5000 signatures and letters of support that were submitted to HC.[151] Eventually, in December 2021, HC announced that the prohibition on accessing psychedelics under SAP would be reverted; these changes came into force on 5 January 2022.[152]

4. *Access to psychedelic-assisted therapies under MAiD provisions*

a. *Regulatory provisions*

In Canada, medical assistance in dying has been permissible since 2016 under conditions specified by statutory law.[153] Those conditions included explicit consent to the termination of life, a person having a grievous and irremediable medical condition, and that person's death being "reasonably foreseeable."[154] At the start of the fifth year after Bill C-14, which brought in the new law concerning MAiD, received royal assent, these provisions were to be referred to a committee of the senate, the house of commons,

With Salvation Botanicals" *Psychedelic Finance* (4 May 2020), online: <psychedelicfinance.com> [perma.cc/4V4T-XHQR].

147. "Health-Canada-Briefing-Note" (20 November 2020), on file with author.

148. *Ibid.*

149. *Ibid.*

150. Health Canada, "Proposal to Restore Potential access to Restricted Drugs Through the Special Access Program" (11 February 2021), online:<canada.ca/en/health-canada/programs/proposal-restore-potential-access-restricted-drugs-special-access-program.html>.

151. Email correspondence with MAPS Canada (May 2022), on file with the author.

152. *Regulations Amending Certain Regulations Relating to Restricted Drugs (Special access Program),* SOR/2021, 271 Gaz II, online: <gazette.gc.ca> [perma.cc/6AGG-NP49].

153. Bill C-14, *An Act to amend the Criminal Code and the make related amendments to other Acts (medical assistance in dying)*, 1st Sess, 42nd Parl, 2015, cl 241.2(1)(d) (assented to 15 June 2016), SC 2016, c 3 [Bill C-14].

154. *Ibid*

or both houses of parliament, for review. The committee was also tasked to review the state of palliative care in Canada and submit a report to the house or houses of parliament and potentially suggest recommended changes to the provisions.[155] This review was supposed to be initiated no later than 180 days after the royal assent, and the report, including findings or recommendations, was to be prepared within two years from the outset of the review.[156] In the meantime, however, the 2019 Quebec Superior Court ruling struck down a provision that limited assisted dying to intolerably suffering individuals whose *death is reasonably foreseeable*.[157] Justice Baudouin issued a suspended declaration for twelve months.[158]

In February 2020, the Minister of Health introduced Bill C-7, *An Act to amend the Criminal Code (medical assistance in dying),* for consideration by Parliament.[159] Bill C-7 proposed three sets of changes. The first was to repeal the provision requiring a person's natural death to be reasonably foreseeable, complying with the *Truchon* decision.[160] It also included a provision to allow access to MAiD via advanced directives (or advanced request) by those whose natural death is reasonably foreseeable and who will have lost the capacity to consent immediately before MAiD is provided.[161] The Bill also directly excluded persons from accessing MAiD whose sole underlying condition is a mental illness.[162] Yet, after a parliamentary debate at the House of Commons, and after hearing several oral and written submissions, amendments to the Bill to extend eligibility for MAiD to persons who have mental illness as an underlying solo condition and expand access to mature minors were proposed.[163] These proposed amendments to the Bill stirred debates in the house of commons and senate.[164] As a result, the Bill that received a Royal Assent on 17 March 2021, at least temporarily, excluded access to MAiD for persons with mental illness as an underlying solo condition and mature minors,

155. *Ibid*
156. *Ibid*
157. *Truchon v Procureur général du Canada*, 2019 QCCS 3792 at paras 734-736.
158. *Ibid.*
159. Bill C-7, *An Act to amend the Criminal Code (medical assistance in dying),* 2nd Sess, 43rd Parl, 2021, c 2 (first reading, 5 October 2020) [Bill C-7].
160. Accordingly, it also proposed two sets of safeguards that must be respected before medical assistance in dying may be provided to a person, the application of which depends on whether the person's natural death is reasonably foreseeable.
161. Bill C-7, *supra* note 159.
162. *Ibid.*
163. *House of Commons Debates*, 43-2, No 14 (19 October 2020), online: <ourcommons.ca > [perma.cc/EWL5-KDHN].
164. See Bill C-7, *supra* note 159. Specifically, read the readings, communications, and other activities in the House of Commons, Senate, and in between them starting from October 2020 until 17 March 2021, see online: <parl.ca> [perma.cc/5SV5-NN4N].

yet included provisions providing that a parliamentary committee would consider the state of palliative care in Canada and protections for people with disabilities, as well as offer recommendations to the inclusions of persons with mental illness in accessing MAiD.[165] However, as far as they relate to access to MAiD for persons with mental illness as a sole underlying condition, these provisions will be repealed on 17 March 2023 or two years after the revision received royal assent.[166]

b. *Assembling access to psychedelics under MAiD*

With the Canadian Parliament scheduled to debate Bill C-7 and the foreseeable five-year parliamentary review on the state of palliative care in Canada, organizations advocating for access to psychedelic-assisted therapies in Canada have used a combination of provisions inscribed in the MAiD law requiring that a medical practitioner (or nurse practitioner) needs to inform the person who requests medical assistance of dying of "means that are available to relieve their suffering, including palliative care," and the "right to try" to argue that psychedelic-assisted therapies should be included as one of the palliative care options a person can consider in deciding whether or not to undergo MAiD.[167] This regulatory pathway was officially initiated with a brief policy submission, *Psilocybin-Assisted Therapy & MAiD a Compassionate Case of Canadians,* prepared for a for-profit company, Field Trip Inc, and submitted to Parliament. The brief recommended that "policymakers consider amendments to Bill C-7 allowing end of life and palliative Canadians the right to legally access psychedelic therapies for non-recreational, medicinal and therapeutic relief."[168]

Field Trip was established in January 2020 in Toronto and was a publicly traded Canadian company.[169] It focused on researching the extraction of psilocybin from mushrooms, a process done in Jamaica under the University of West India's umbrella and operated ketamine clinics in Canada and the US.[170] Its founders came from cannabis, gold training, and banking and investing industries.[171] In the summer of 2021, a few non-profit and for-profit organizations, led by the Canadian Psychedelics

165. *Ibid*.
166. *Ibid.*
167. Bill C-14, *supra* note 153.
168. In the Committee Stage of Bill C-14, this brief was submitted by Kydder Group Inc on behalf of Field Trip Inc: Standing Committee on Justice and Human Rights (25 November 2020), online: <ourcommons.ca> [perma.cc/PMF3-D4Z7].
169. Will Yakowicz, "Field Trip Health, Another Psychedelics Therapy Company Goes Public," *Forbes* (7 October 2020), online:<forbes.com> [perma.cc/BDJ9-2EGR].
170. *Ibid*.
171. *Ibid*.

Association (CPA), formed a "MAiD coalition" or a "regulatory alliance," of which Field Trip was a part, to advocate for the inclusion of access to psychedelic therapies under committee's recommended amendments to the MAiD legislation.[172] Removing Field Trip from leading the MAiD effort was explained to me by a person involved in launching the alliance as a strategic move not to have a commercial entity heading a pathway for compassionate access.[173] Between November 2020 and July 2021, members of the CPA met with members of parliament to advocate for legally controlled access to psilocybin-assisted therapy and with the MAiD Parliamentary Review Committee. As a part of this campaign, the CPA contracted Nanos to conduct a poll surveying the support for psilocybin-assisted therapies among the Canadian population.[174] This poll was planned for regulatory purposes for MAiD and beyond.[175] Due to the federal election scheduled for Fall 2021, further work on MAiD law in parliament was put on hold with plans to resume in Spring 2022 to hear the results of the parliamentary review.

Conclusion

While the current regulatory landscape is characterized by a few critical organizational actors, primarily working in collaboration with MAPS, who use their knowledge and financial resources to establish connections with multiple actors in Canada's psychedelics landscape, this landscape is subject to constant changes as new entities get enrolled into regulatory networks. MAPS's history back to prohibition and the "War on Drugs" positioned this organization as a leader in the psychedelics landscape in the USA and Canada. Some other Canadian companies emerged off its strings (and remain part of the MAPS' network), building on the institutional knowledge and clinical trials that MAPS has acquired and developed over time. By tracing relations mobilized for "producing" psychedelic therapies as a medical and legal object, it is possible to see how domination and professionalization, and the likely future market share, in the context of these therapies, is being enacted with resultant implications for who can access them and under what conditions.

While the therapeutic potential of psychedelics led investors and entrepreneurs from pharmaceutical, cannabis and general investment

172. Canadian Psychedelic Association, "We launched an initiative suggesting the inclusion of psychedelics as an option for mental wellbeing, and which aims to help…" (16 July 2021), online:<twitter.com> [perma.cc/D5L6-CAQN]; Fieldnotes: 23 May 2021, 29 June 2021 and email correspondence: 16 July 2021; Fieldnote, 7 July 2021.

173. Interview, 13 August 2021.

174. Fieldnote, *supra* note 172.

175. *Ibid.*

groups to invest en mass, this market is very fragile, and the revenue-generating pathways are rather promissory than certain.[176] The highest and the most rapid projected growth of medical psychedelics market revenues is expected from MDMA-assisted therapies pioneered by MAPS. Those are the most advanced clinical trials (already in the second leg of stage III), with an expected U.S. FDA approval in 2023. Currently, MDMA is available for compassionate access in the USA through its Expanded Access Program in Israel and Canada through pathways discussed in this paper. However, to roll out psychedelic therapies on a temporary basis under compassionate access or a permanent basis as market-approved interventions requires significant investment and infrastructure development. For example, scaling up psychedelic therapies will require thousands of new therapists to be trained to deliver psychedelic services under the professionalized model, which requires providers to be trained in specific psychedelic-therapy protocols. Yet, as discussed above, the training opportunities for Canadian therapists are limited. Thus, the alliances and collaborations established by actors involved in psychedelic advocacy carry significance beyond the regulatory field. They also allow various organizations and their therapists to access competitive training on a preferable basis, ahead of others. For instance, trainers from Numinus had a priority admission to MAPS training because of the planned extension of MAPS clinical trials for PTSD under compassionate trial, which was to be run by Numinus in its clinics in Vancouver.

These entanglements and nodes between the regulatory pursuit in Canada and organizations' strategic positioning for psychedelic therapies rollout need to be investigated further to shed light on the future access to psychedelic interventions in Canada. Such work can help unveil some of the complex entanglements between psychedelic regulation, advocacy, and commercial interests as bound up in the legalization of psychedelic-assisted therapies in Canada and problematize the current dominant narrative around the development of psychedelic medicine as an enterprise-compassion-driven.

176. Report 2021, *supra* note 25.