



*Citation for published version:*

Freeman, TP, Mehta, MA, Neill, JC, Nutt, DJ, Tunbridge, EM & Young, AH 2018, 'Restrictions on drugs with medical value: Moving beyond stalemate', *Journal of Psychopharmacology*, vol. 32, no. 10, pp. 1053-1055. <https://doi.org/10.1177/0269881118798609>

*DOI:*

[10.1177/0269881118798609](https://doi.org/10.1177/0269881118798609)

*Publication date:*

2018

*Document Version*

Peer reviewed version

[Link to publication](#)

Freeman, Tom P ; Mehta, Mitul A ; Neill, Joanna C ; Nutt, David J ; Tunbridge, Elizabeth M ; Young, Allan H. / Restrictions on drugs with medical value : Moving beyond stalemate. In: *Journal of Psychopharmacology*. 2018 ; Vol. 32, No. 10. pp. 1053-1055. Copyright (C) 2018 The Authors. Reprinted by permission of SAGE Publications.

**University of Bath**

**Alternative formats**

If you require this document in an alternative format, please contact:  
[openaccess@bath.ac.uk](mailto:openaccess@bath.ac.uk)

**General rights**

Copyright and moral rights for the publications made accessible in the public portal are retained by the authors and/or other copyright owners and it is a condition of accessing publications that users recognise and abide by the legal requirements associated with these rights.

**Take down policy**

If you believe that this document breaches copyright please contact us providing details, and we will remove access to the work immediately and investigate your claim.

**Restrictions on drugs with medical value: moving beyond stalemate**

Journal:	<i>Journal of Psychopharmacology</i>
Manuscript ID	JOP-2018-3596
Manuscript Type:	Editorial
Date Submitted by the Author:	08-Aug-2018
Complete List of Authors:	Freeman, Tom; Institute of Psychiatry, Psychology & Neuroscience, National Addiction Centre; University of Bath, Department of Psychology Mehta, Mitul; Institute of Psychiatry, Centre for Neuroimaging Sciences Neill, Joanna; Manchester University, Manchester PHarmacy School Nutt, David; Imperial College , Neuropsychopharmacology Tunbridge, Elizabeth ; University of Oxford, Department of Psychiatry Young, Allan; Imperial College London, Centre for Mental Health
Please list at least 3 keywords which relate to your manuscript::	Schedule 1, Cannabis, MDMA, Psilocybin, British Association for Psychopharmacology
Abstract:	N/A

# Restrictions on drugs with medical value: moving beyond stalemate

Tom P Freeman<sup>1,2\*</sup>, Mitul A Mehta<sup>3</sup>, Joanna C Neill<sup>4</sup>, David J Nutt<sup>5</sup>, Elizabeth M Tunbridge<sup>6</sup>,  
Allan H Young<sup>7</sup>

1. National Addiction Centre, Institute of Psychiatry, Psychology & Neuroscience, King's College London, UK
2. Department of Psychology, University of Bath, UK
3. Department of Neuroimaging, Institute of Psychiatry, Psychology & Neuroscience, King's College London, UK
4. Division of Pharmacy and Optometry, School of Health Sciences, University of Manchester, Manchester, UK
5. Neuropsychopharmacology Unit, Division of Brain Sciences, Imperial College London, London, UK
6. Department of Psychiatry, University of Oxford, and Oxford Health NHS Foundation Trust, Warneford Hospital, Oxford, UK
7. Department of Psychological Medicine, Institute of Psychiatry, Psychology & Neuroscience, King's College London, UK

\*Address correspondence to:

Tom Freeman  
National Addiction Centre  
King's College London  
4 Windsor Walk, London SE5 8BB  
[tom.freeman@kcl.ac.uk](mailto:tom.freeman@kcl.ac.uk)

Keywords: Schedule 1, Cannabis, MDMA, Psilocybin, British Association for  
Psychopharmacology

1  
2  
3 A key task for psychopharmacology is to establish which medicines can provide optimal  
4 clinical benefit with minimal levels of harm. Drugs that are considered to have no medical  
5 value and a high risk of misuse or harm are listed in Schedule 1 of the UK Misuse of Drugs  
6 Regulations 2001; these currently include cannabis, 3,4-methylenedioxymethamphetamine  
7 (MDMA) and psilocybin. Schedule 1 drugs cannot be possessed or prescribed by clinicians,  
8 and research is only permitted under a Home Office license that is costly and time intensive  
9 to obtain.  
10  
11  
12  
13  
14  
15  
16  
17  
18

19  
20 By contrast, drugs that are deemed to have medical value despite a high liability for misuse or  
21 harm are placed in Schedule 2, including diamorphine, cocaine, amphetamines and ketamine.  
22 Research on these drugs is less restricted. They can be legally possessed by people with a  
23 prescription and possessed and supplied by pharmacists, doctors and dentists. Restrictions are  
24 lower still for drugs with widespread medical use listed in Schedules 3 to 5 such as  
25 buprenorphine and diazepam. In light of accumulating evidence supporting the medical value  
26 of Schedule 1 drugs including cannabis (Whiting et al., 2015), MDMA (Mithoefer et al.,  
27 2018) and psilocybin (Ross et al., 2016), this legislation creates a barrier to research and the  
28 advancement of medical science.  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40

41 As part of a three-year commission from the Home Secretary, the Advisory Council for the  
42 Misuse of Drugs (ACMD) has been engaged in consultations on how research using Schedule  
43 1 drugs might be facilitated. Based on their initial consultations, several suggestions were  
44 raised by the research community. These included a blanket exemption from Schedule 1 for  
45 research (like the Psychoactive Substances Act 2016) or the provision of a single  
46 organisational licence to bring exemption from Schedule 1 requirements for academic  
47 institutions.  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

1  
2  
3  
4  
5 To capture the views of the British Association for Psychopharmacology (BAP) in these  
6 consultations, we conducted a survey in May 2018 on our members' experiences of  
7 conducting research using controlled drugs. We received 23 detailed responses from  
8 members with a range of backgrounds, including those in a clinical, preclinical and industrial  
9 setting. Only two of these 23 respondents had no suggestions for improvement.  
10  
11  
12  
13  
14

15 Overwhelmingly, our members consider that the current legislative framework requires  
16 improvement to facilitate research. Specifically, Home Office licenses were reported to be  
17 prohibitively costly (requiring both an initial and renewal fee, and highly specific and costly  
18 requirements for storage). Furthermore, they were reported to create an unnecessary  
19 administrative burden and significant delays that could not be scientifically justified, given  
20 the low levels of risk compared to Schedule 2 drugs such as diamorphine (heroin).  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30

31 To give specific examples, in some cases the Home Office had requested ethical approval  
32 before granting an initial license; however, the relevant ethics committee had in turn  
33 requested Home Office approval before accepting an application - a classic Catch 22 situation  
34 - causing significant frustration, excess paperwork and long delays. From an industry  
35 perspective, our members reported that opportunities to work internationally had to be  
36 declined due to the excessive costs associated with the multiple import and export licenses  
37 required under the current framework. The limited duration of import and export licences  
38 raised further challenges. Our members suggested that research councils should be made  
39 aware of these issues, as it may be necessary to request additional resources and time to  
40 complete research studies. As one respondent put it: *"As it stands, it is so difficult to even  
41 contemplate research in this area as you almost have to think 'Right, we might, if all goes  
42 well, be able to start in 2 years.'"*  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

1  
2  
3  
4  
5 Several respondents pointed out that the current system is unnecessarily burdensome for  
6  
7 researchers working with small quantities of Schedule 1 drugs. The Misuse of Drugs  
8  
9 Regulations 2001 lists an exemption for small quantities. However, apart from lysergide or  
10  
11 any other *N*-alkyl derivative of lysergamide (1 microgram) there is no drug-specific level of  
12  
13 exemption, and 1 milligram applies to all drugs. Problems were reported with obtaining a  
14  
15 small quantity of a cannabinoid (total 10mg delta-9-tetrahydrocannabinol), leading to  
16  
17 significant delay of a PhD student's submission and their supervisor, an Associate Professor  
18  
19 of psychiatry, deciding to abandon this line of research altogether: *"In short, I can tell you  
20  
21 without hesitation that the current legislation surrounding controlled drugs is stifling  
22  
23 research in this area: it has essentially dissuaded me from continuing my work. I no longer  
24  
25 work on controlled drugs."*

26  
27  
28  
29  
30  
31 In contrast, experiences of working with Schedule 2 drugs were reported more favourably,  
32  
33 providing a potential framework for legislation moving forwards: *"We routinely use schedule  
34  
35 II drugs for experiments in animals. Process for ordering and management work well.  
36  
37 Schedule I drugs are much more difficult due to additional licensing which effectively  
38  
39 precludes use using these compounds despite potential value for preclinical research."*

40  
41  
42  
43  
44 Notably, the additional restrictions for Schedule 1 drugs was not considered scientific or  
45  
46 appropriate given the level of risk: *"The difference in regulations for using Schedule 2 drugs  
47  
48 e.g. PCP and Schedule 1 drugs e.g. cannabinoids, and difficulty in using Schedule 1 drugs is  
49  
50 not evidence based or scientific. The current UK drug laws are clearly hindering research at  
51  
52 all levels."* Although the ACMD initially considered that a blanket exemption of Schedule 1  
53  
54 restrictions for the research community would not be workable, feedback from our survey  
55  
56  
57  
58  
59  
60

1  
2  
3 highlighted that a similar exemption already exists, as University research departments are  
4  
5 not required to hold a Home Office license to possess and supply drugs in Schedules 2 to 5. It  
6  
7 was argued that extending this exemption to Schedule 1 should not be problematic or lead to  
8  
9 “unintended consequences”.

10  
11  
12  
13  
14 Shortly after our survey was completed, a high-profile case emerged in which a 12-year old  
15  
16 boy named Billy Caldwell and his mother travelled to Canada to obtain cannabis oil to  
17  
18 control his epileptic seizures. When they returned to the UK on June 11<sup>th</sup> 2018, the cannabis  
19  
20 oil was confiscated by the Home Office. The situation escalated when Billy was admitted to  
21  
22 hospital with severe and potentially life-threatening seizures, resulting in an unprecedented  
23  
24 decision from the Home Office to return the cannabis oil on June 16<sup>th</sup>. The Home Secretary,  
25  
26 Sajid Javid, commissioned a two-stage review on medicinal uses of cannabis products, and a  
27  
28 coalition of academics and clinicians led by several members of the BAP called on the  
29  
30 government remove them from Schedule 1.  
31  
32  
33  
34  
35  
36  
37

38 The first stage of the review conducted by Chief Medical Officer Sally Davis stated: *“There*  
39  
40 *is now however, conclusive evidence of the therapeutic benefit of cannabis based medicinal*  
41  
42 *products for certain medical conditions and reasonable evidence of therapeutic benefit in*  
43  
44 *several other medical conditions... As Schedule 1 drugs by definition have little or no*  
45  
46 *therapeutic potential, it is therefore now clear that from a scientific point of view keeping*  
47  
48 *cannabis based medicinal products in Schedule 1 is very difficult to defend.”* The second  
49  
50 stage of the review conducted by the ACMD agreed with this conclusion, recommending that  
51  
52 cannabis-derived medicinal products (once clearly defined) should be moved from Schedule  
53  
54 1 to Schedule 2.  
55  
56  
57

1  
2  
3  
4  
5  
6 Home Secretary announced on 26<sup>th</sup> July 2018 that cannabis-derived medical products would  
7  
8 be moved Schedule 2. He should be commended for rapidly commissioning these two  
9  
10 reviews, and for informing his decision using scientific evidence. This historical move broke  
11  
12 the longstanding and illogical stalemate of holding drugs with medical value in Schedule 1.  
13  
14 In their commissioned review, the ACMD also concluded that: *“it is important that cannabis*  
15  
16 *is not seen in isolation but as an example of a wider issue of potential ‘barriers to research’*  
17  
18 *associated with other drugs in Schedule 1.”* In light of the efficiency with which cannabis  
19  
20 products were reviewed - and the clear conclusions reached - we now hope that scientific  
21  
22 evidence and review can challenge the Schedule 1 status of other potential medicines,  
23  
24 including MDMA and psilocybin.  
25  
26

27  
28 In conclusion, the results of our survey clearly demonstrate that current UK legislation  
29  
30 hampers research into the consequences, and potential therapeutic benefits of Schedule 1  
31  
32 drugs. We praise the government’s rapid response to cannabis based-medicinal products, and  
33  
34 hope this will encourage further debate about the Misuse of Drugs Regulations and its impact  
35  
36 on the field of psychopharmacology.  
37  
38

39  
40 Acknowledgements: TF was funded by a senior academic fellowship from the Society for the  
41  
42 Study of Addiction (SSA). AY was funded by the National Institute for Health Research  
43  
44 (NIHR) Biomedical Research Centre at South London and Maudsley NHS Foundation Trust  
45  
46 and King’s College London. The views expressed are those of the authors and not necessarily  
47  
48 those of the SSA, NHS, the NIHR, or the Department of Health.  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60



1  
2  
3 Conflicts of interest: All authors are officers or council members of the British Association  
4 for Psychopharmacology (BAP). For a regularly updated list of their declarations of interest,  
5 please refer to the BAP website: <https://www.bap.org.uk/council.php>  
6  
7  
8  
9

10 Mithoefer, M. C., Mithoefer, A. T., Feduccia, A. A., Jerome, L., Wagner, M., Wymer, J., . . .  
11 Emerson, A. (2018). 3, 4-methylenedioxymethamphetamine (MDMA)-assisted  
12 psychotherapy for post-traumatic stress disorder in military veterans, firefighters, and  
13 police officers: a randomised, double-blind, dose-response, phase 2 clinical trial. *The*  
14 *Lancet Psychiatry*, 5(6), 486-497.

15  
16 Ross, S., Bossis, A., Guss, J., Agin-Liebes, G., Malone, T., Cohen, B., . . . Babb, J. (2016).  
17 Rapid and sustained symptom reduction following psilocybin treatment for anxiety  
18 and depression in patients with life-threatening cancer: a randomized controlled trial.  
19 *Journal of Psychopharmacology*, 30(12), 1165-1180.

20 Whiting, P. F., Wolff, R. F., Deshpande, S., Di Nisio, M., Duffy, S., Hernandez, A. V., . . .  
21 Ryder, S. (2015). Cannabinoids for medical use: a systematic review and meta-  
22 analysis. *JAMA*, 313(24), 2456-2473.  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60