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The Rt Hon Kit Malthouse MP
Minister of State (Minister for Crime and Policing)
2 Marsham Street,
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The Rt Hon Sajid Javid MP
Secretary of State for Health and Social Care
39 Victoria Street,
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22nd February 2022

Dear Mr Malthouse and Mr Javid,

It has come to our attention that the Home Office is aware of the issues surrounding psilocybin's current scheduling under the Misuse of Drugs Regulations 2001. Research into its potential—as a medicine and as an experimental tool—is all but foreclosed to numerous UK higher education institutions and businesses. This is a serious and easily corrected situation which requires action, it is our recommendation that the Chief Medical Officer assess the evidence for the harms and utility of psilocybin with a view to rescheduling to Schedule 2 with restrictions to prevent inappropriate prescribing while facilitating research in the UK.

Recently Compass Pathways, a British company listed on the NASDAQ, published the topline results of their phase IIb trial of psilocybin for treatment resistant depression - with impressive results. This is the largest randomised, controlled, double-blinded trial to look at psilocybin and has raised hopes that it could become a safe and effective medical product. The results of this trial show that psilocybin-assisted therapy can have rapid and durable clinically significant effects on severe depression. Most of the participants who received the 25mg dose of psilocybin, alongside psychotherapy, experienced reductions in symptoms from the first assessment post-dose (day 2) for upto 12 weeks. It is worth mentioning that this is after a single dose of a drug that remains on the site of the hospital in which it is administered, meaning the chances of diversion are extremely low; especially when one considers that there is no evidence of increased diversion of Schedule 2 controlled substances from research settings compared with those in Schedule 1.

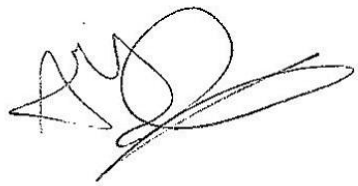
Psilocybin's promise lies not only in its potential as a treatment for depression but as an adjunct to the psychotherapeutic treatment of a variety of internalising disorders which implicate similar psychological

mechanisms and brain regions. This compound is now being investigated as an adjunct to the psychotherapeutic treatment of anorexia nervosa, obesity, post traumatic stress disorder and addictions to alcohol, cocaine and tobacco. If research was to be facilitated, we may come to learn that many other psychiatric disorders could be amenable to this novel treatment option. But psilocybin's utility should not to be thought of as restricted to its administration as a medicine. When administered as a pharmacological challenge, changes in brain activity can be brought to light that inform our understanding of functional brain architectures and processing, advancing human knowledge and translational applications. The Schedule 1 designation of psilocybin and the other psychedelics is having the profound effect of impeding this kind of research, as many institutions simply do not have the economic and temporal resources to secure the necessary licenses. Frustratingly, the Home Office's position which appears to be that it will only look at rescheduling when a product reaches market authorisation, is not stipulated in law and is inconsistent with the precedent set by cannabis based products for medicinal use in 2018.

While the upcoming ACMD review of barriers to researching Schedule 1 drugs may make recommendations which go some way to addressing the barriers to research faced by UK scientists, for which we are grateful, another pertinent issue presents itself. The Government has confirmed that there has been no recent review of the evidence for psilocybin's current scheduling. Having assessed the evidence and history of this legislation ourselves, we understand that there is not and has never been an evidential basis for psilocybin's current scheduling, based as it is on the UN Single Convention on Psychotropic Substances 1971. This is strange given the emerging evidence of psilocybin's therapeutic potential and clear neuroscience research utility.

We feel it is our duty as independent experts in the field of psychiatry and neuroscience to request you commission the Chief Medical Officer assess the evidence for the harms and utility of psilocybin with a view to rescheduling this promising medicine and experimentally useful compound at the earliest opportunity.

Yours, with best wishes,



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