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MEDICINE

DEPARTMENT OF PSYCHIATRY AND BEHAVIORAL SCIENCES

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To Sen. Brian Schatz:

I applaud your efforts to help address the substantial regulatory hurdles that prevent or drastically slow research into the health effects of cannabis and other exogenous cannabinoids. As you are aware, this research us an urgent need for our country at a time when most Americans are able to purchase products for medicinal use in the absence of clear data to determine the safety or efficacy of that decision, to guide clinical decision making regarding dose or route of administration, and when products are being produced and labeled in the absence of research-based standards.

I have encountered several barriers in the conduct of my research studies over the past several years. For studies in which we have highlighted inaccuracies in cannabis product labeling, we were denied any means of possessing the products that we had tested. We were required to orchestrate those studies from a distance, and without using federal funds. The results of those studies, however, demonstrated that there are glaring issues with product labeling and drug concentration, which are serious public health concerns.

Controlled laboratory studies that I conduct have been repeatedly delayed due to extensive and redundant regulatory requirements. It takes me 6-12 months to gain approvals to begin a new study involving the administration of cannabis or other cannabinoids to healthy human volunteers. Much of this time is that DEA requires us to submit every new study to them for a separate approval, and this can only be submitted after we obtain all other regulatory approvals (IRB, NIH, FDA). This is completely redundant and makes no sense given that there has been no change in our security or handling of controlled substances for decades. It is also unclear why DEA cannot review new protocols in parallel with submissions to other regulatory agencies.

Another issue is the existence of multiple Schedule I drug codes for related products, and the process for adding these codes to a license. For example, I currently have a Schedule I license for cannabis. This also covers pure synthetic CBD, which I am studying. Recently, I submitted a protocol to study pure, synthetic THC. This required a formal review of my study, an inspection of our facility, and it was more than 3 months before I was granted approval. All this took place while I had cannabis, containing high concentrations of THC, in my lab. In another perplexing case, in order to launch a new study using a CBD extract, derived from cannabis, I need to get yet another new drug code added to my Schedule I license. The drug code for pure CBD and cannabis does not cover extracts of cannabis containing CBD. THC is currently in Schedules I, II, and III of the CSA. CBD is in Schedules I and V. All this is seemingly arbitrary and makes no sense.

Another issue is that, due to the extensive bureaucracy, there is a scarcity of products available for use in these studies. For example, this year I have been unable to find an open domestic source of pure THC or CBD for a human research. As researchers, we must rely on gaining access to these substances from pharmaceutical companies that are manufacturing it, and often they deny our requests to obtain them or they request absurd amounts of money. I am unaware of any source of other minor cannabinoids (e.g. CBG, CBC, CBN, THC-V) that are suitable for

human research. This is a major barrier for the conduct of much needed science to understand the impact of constituent components of the cannabis plant.

There must be drastic changes to federal policy on cannabis/cannabinoid research. Scientists must be granted access to retail products being sold to millions of Americans in order evaluate the risks and benefits of their use. This will require a mechanism for Schedule I license holders to bring retail cannabis products into the federal chain of custody for controlled substances. Regulatory science must be conducted to ensure that cannabis legalization and use at the state level occurs in a manner that is in the best interest of public health. Scientists must be able to access materials relevant to evaluating the effects of individual chemical constituents of the cannabis plant. All of this needs to happen in a manner that maintains the integrity of the scientific process and ethical research (e.g. maintenance of the requirements of FDA and IRB review of clinical trials and IACUC approval of pre-clinical research). But there needs to be recognition that the amounts of cannabis/cannabinoids needed to conduct these studies are usually very small, that these substances are widely available to the public through unregulated or very loosely regulated markets, and that there is currently no indication that CBD is a drug of abuse. Currently, the oversight and review requirements for cannabis/cannabinoid are unreasonable, and are resulting in substantial delay in the conduct of basic science that can improve public health as well as the evaluation of a drug industry that has exploded in size, complexity, and influence in the absence of appropriate research, regulation and oversight.

If you have any questions or if I can be of any additional assistance in this, please let me know.
Regards,

Ryan Vandrey, PhD