Tuesday, July 19, 2022

RE: Proposed scheduling of DIPT

To Whom It May Concern:

I am writing this account at the request of Jason Wallach, PhD and Hamilton Morris to characterize my experience in organizing, soliciting and managing primary chemistry work with numerous scheduled and unscheduled molecules in early pharmaceutical development.

As background, I am a physician psychiatrist and Chief Scientific Officer at Bexson Biomedical, Inc., an early pharmaceutical development biotechnical firm focused upon development of medical therapies for subcutaneous delivery. We primarily employ repurposing strategies to convert IV-only medications to this new route of administration. Bexson is developing numerous early stage drug formulations for pairing with a wearable patch pump and/or dose metered pen injectors to actuate a number of potential life-saving subcutaneous therapies for long-felt unmet need.

Bexson's initial mission in forming was to address the National Health Crisis surrounding opioid addiction, overdose and death that claimed over 100K Americans in 2021. Towards that goal, we are developing non-opioid pain management therapies and a number of new addiction treatments. After five years ,we are preparing our two IND applications to the FDA, have another planned, and have numerous other, early-stage pharmaceutical formulations for further potential development or licensing.

While I do not handle these molecules or therapies directly, I have direct experience in contracting and directing early benchtop research and developing both scheduled and non-scheduled molecular therapies such as:

- naloxone for opioid overdose or for battlefield protection against weaponized opioids
- flumazenil for benzodiazepine dependence and battlefield protection against weaponization
- Antibiotics for resistant bacteria and long-term infectious disease management in at-home settings
- Ketamine for post-operative pain management and mental health indications
- $5HT2_A$ agonist (i.e., psychedelics) therapies for mental health indications, post stroke recovery and rehabilitation, and CNS pain disorders such as migraine and cluster headaches

In short, I have had the chance to directly witness the regulatory ease or difficulty of performing early research and development with molecules of different scheduling classes. We have worked with approximately 25 different molecules with status ranging from nonscheduled to schedules I, II and III. I have also witnessed the differences in the direct and indirect cost of research and the precious time lost in research regarding these different classes. I will illustrate with the following examples.

Bexson Biomedical has contracted with Thermo Fisher Scientific for early research on a number scheduled and non-scheduled therapies. Because schedule I medications are nearly impossible to purchase in the quantity required for early benchtop research (e.g., 10-50 grams), Bexson was forced to contract for direct synthesis of these molecules (i.e., DMT, 5-MeO-DMT and Mescaline) at approximately $50K/50G for each molecule. This is in direct and stark contrast to our experience contracting for development of a ketamine formulation for post-operative pain management, the raw material for which costs 750X less even though it is schedule III. Perhaps less dramatic, but nevertheless important in regards the allocation of resources in early pharma development, was

our experience with flumazenil, a highly potent and relatively rare but important medication approved for rescue from benzodiazipine (e.g., Valium™, Klonopin™) overdose. We believe that our program actuating this medication for benzodiazepine dependence represents a badly needed treatment for Americans and were pleased that we could source raw material at 30X less expense than the schedule I molecules we also targeted for mental health addiction treatments.

The following are a few examples of prices paid by our program for raw API in early development processes:

- SCHEDULE I:
    1. Mescaline $47,500/50G
- SCHEDULE III:
    1. Ketamine HCl $37/50G
- NON-SCHEDULED:
    1. Naloxone HCL at $1,650/50G
    2. Eletriptan HBr $1,800/50G
    3. Flumazenil HCl $1,650/50G

Drug development is a very expensive process, and as can be seen from the illustration of cost differences above, the real-world consequences of schedule I status upon pricing of raw API are so severe as to place these out of reach in most normal development programs.

In addition, it is not just the raw API prices that create potentially notable barriers to development. Working with schedule I substances requires licensure, reporting and diligence that places heavy cost burdens upon any research project, both through real costs passed onto the developer and a premium placed upon bids due to the scarcity of research labs willing to deal with the regulatory burdens. It can be difficult to find even two or three contract chemical research firms to entertain a bid for this type of work, allowing the few contractors that do exist to charge vastly more than what they would for other non-scheduled projects. Also due to scarcity, these contractors are busy enough that they can cherry prick the projects the accept, leaving early stage developers without partnership option.

Regarding real world consequences in early drug development, where research is funded by investors and philanthropy, these stark layered pricing realities create an environment wherein early research into potential new and important therapies for human kind is often inhibited and is commonly stopped outright. Even for a company like ours, specifically dedicated to developing badly needed new treatments in human addiction and pain management, the realities I am describing can be undeniable.

To illustrate this specifically, after allocating approximately 1.5 years of internal human capital and around $150K towards development of mescaline—a safe, well-researched psychedelic with history of efficacy in treatment of resistant alcoholism, Bexson Biomedical was forced to abandon development due to excessive costs and difficulty finding a contract research organization to work with. We are disheartened by this development for many reasons, not the least of which is the loss of a potential treatment for a devastating illness affecting tens of millions of Americans.

In summary, I hope through offering this account that the agencies involved in regulating and controlling chemicals in the United States consider prudence and use of evidence based decisions to justify placement of any further restrictions upon this class of molecule/medication. The consequences of the currently proposed new scheduling are potentially both direct and severe for

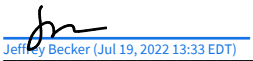
American medical advancement. It is clear that the classical psychedelics (i.e., the $5HT2_A$ agonists) represent new, ground-breaking treatments for many conditions that currently cause layers of morbidity and mortality in Americans, documented everyday day by our CDC.

The U.S. has always been a location for innovation and advancement in medicine. It would be a shame for American biopharmaceuticals to be shut of a promising movement in research regarding new treatments for Depression, Post-Traumatic Stress Disorder, Pain, Addiction, stroke rehabilitation, Age-Associated Memory Loss, Parkinson's Disease, autoimmune disease, suicide, etc. This class of molecules is almost universally non-addictive, even "anti-addictive," and I hope that new, research-chilling scheduling does not place them out of reach as new treatments for life-threatening illness.

Sincerely,

Jeffrey Becker, MD
Physician Psychiatrist
Bexson Biomedical, Chief Scientific Officer

I hereby declare, under penalty of perjury ((18 U.S.C. § 1621 28 U.S.C. § 1746)) that my testimony in the foregoing document is true and correct."



Dr. Jeffrey Becker, M.D.

The Parties Dr. Jason Wallach and Hamilton Morris hereby move for the admission of this testimony in the trial of this cause, The parties further pray this Honorable Court to permit further examination of this witness on matters outside of the scope of this testimony in the event that the proceedings necessitate same for the purposes of rebuttal. Finally, the Parties pray for any and all other relief this Court deems fit in law or equity.

Dated: July 19, 2022

Respectfully submitted,

/s/ John T. Hunter
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Attorney

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CERTIFICATE OF SERVICE

I hereby certify that on July 19, 2022, I electronically submitted the foregoing, along with Dr. Halberstadt's June 21, 2022 letter with its accompanying declaration to the DEA Office of the Administrative Law Judges via the DEA Judicial Mailbox, at ECF-DEA@dea.gov, DEA.Registration.Litigation@dea.gov and simultaneously to the Government and fellow Objectors at:

- David Locher and Andrew Winler, attorneys for the DEA, at David.M.Locher@dea.gov and Andrew.T.Winkler@dea.gov
- Matthew C. Zorn, Esq., Counsel for Tactogen Inc. and Mindstate Design Labs, via email at mzorn@yettercoleman.com;
- Graham Pechenik, Esq., Counsel for Tactogen Inc. and Mindstate Design Labs, via email at graham@calyxlaw.com;
- David Heldreth, CEO of Panacea Plant Sciences, via email at davidh@panaceaplantsciences.net;

/s/ *John T. Hunter*

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Final Audit Report 2022-07-19

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