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VYRIPHARM
BIOPHARMACEUTICALS

Docket No. FDA-2018-N-1072 for “International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; Cannabis Plant and Resin; Extracts and Tinctures of Cannabis; Delta-9-Tetrahydrocannabinol (THC); Stereoisomers of THC; Cannabidiol; Request for Comments.”

To the Food and Drug Administration (FDA) for consideration in preparation for a response to the World Health Organization (WHO) regarding the abuse liability and diversion risk for Cannabis Plant and Resin; Extracts and Tinctures of Cannabis; Delta-9-Tetrahydrocannabinol (THC); Stereoisomers of THC; Cannabidiol; Request for Comments.”:

The three undersigned, Dr. Jerry Bryant, Jr., Chief Scientific Officer of Vyripharm Biopharmaceuticals and Andrew Freedman, Director at Freedman & Koski and former Director of Marijuana Coordination for the Governor of Colorado, and Lewis Koski Director at Freedman & Koski and former Director of the Colorado Marijuana Enforcement Division, write to you today strongly urging you to recommend scheduling changes for medical marijuana in order to let policy and science best address abuse potential, actual abuse, medical usefulness, and diversion.



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By way of background, Mr. Freedman was Governor Hickenlooper's point person in the implementation of regulated medical and adult-use marijuana for the state of Colorado. Mr. Koski was the chief regulator for Colorado marijuana system. Dr. Bryant is a co-founder of a biopharmaceutical company currently valued at over \$100 million and devoted to bringing scientific rigor and quality control to the use of marijuana as a medicine.

This letter is not intended to promote Vyripharm. There are other biopharmaceutical companies with technologies that could prove very useful in this area. We present a quick overview of two of Vyripharm's products only to help us demonstrate the value rescheduling will have on promoting public health and public safety.

Vyripharm's capabilities:

Molecular imaging agent: Vyripharm's molecular imaging (Real time Diagnostics) agent provides a predictive assay to measure the effectiveness of the drug in real time. This ability to image solves the problem of diagnosis and therapeutic dosing errors by providing molecular diagnostic and personalized targeted therapy for patients suffering from neurological disorders and cancers. The molecular imaging agent is a unique tool for studying the medical efficacy of any combination of cannabinoid profiles.

Data platform: Vyripharm has the only patented (# 9,632,069 B2) fully comprehensive block-chain botanical testing and evaluation platform. Regulatory adoption of such a platform would ensure quality control, quality assurance, verification, validation, and adoption of pharmaceutical grade standards.

With the correct use of this technology, a rescheduling of cannabis will prevent potential and actual abuse of marijuana, lead to discoveries of medical usefulness, and prevent diversion far better than our current systems of prohibition and state-led legalization efforts.

Preventing Potential and Actual Abuse

Those concerned with any change to current marijuana laws argue that doing so will lead to increased youth use, heavy-use adult consumption, and an increase in DUIs. For all three of these areas, we use Colorado as a data point for whether the concern is valid. Additionally, we



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provide analysis on how the use of technologies outlined above would help alleviate these abuses.

Heavy-use adult consumption

Concerns exist about whether legalization leads to increases in marijuana substance abuse (whether defined as functional impairment, cannabis use disorder, or daily usage). Right now, answers to such questions are scant. However, at least one survey from Colorado shows that approximately 50% of past-30 day users self-report as heavy users.¹ This is a concerning statistic, though it does not yet show a trend line.

Utilizing Vyripharm to control dosing and cannabinoid profiles: The opioid epidemic shows us how the over prescription of opioids led to acute and long term problematic usage. Under the status quo, those self-medicating with marijuana do not know the correct cannabinoid profiles nor the correct dosage. With such information, doctors could better target marijuana usage for patients, limiting THC where appropriate and decreasing the likelihood a patient will develop an addiction. It should also be noted that doctors may then also substitute opioids for marijuana, thus decreasing the far larger problem of opioid addiction.

Youth Use

Data collection about the effect of legalization on youth use is still early.² The good news is two of the main public health surveys from legalized states, Healthy Kids Colorado and Monitoring the Future, have not shown a statistically significant change in youth consumption rates. Also, the NSDUH has shown a significant decrease to date.³ However, it would be premature to draw conclusions from these data as trends can take many years to develop. Some worry that relaxing controls over marijuana may increase access for youth.

Utilizing Vyripharm to monitor the supply chain and limit the use of marijuana to legitimate

¹ <https://cdpsdocs.state.co.us/ors/docs/reports/2016-SB13-283-Rpt.pdf>

² <http://www.greenstate.com/health/a9874166/debunker-legalizations-effect-on-teen-use-hazy-at-best>

³ <http://reason.com/blog/2017/12/12/contradicting-prohibitionists-survey-say>



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medical purposes: As discussed in more detail in the “diversion” section below, the regulatory use of Vyripharm’s data platform, along with other seed-to-sale technologies, will aid in ensuring that marijuana is only being sold for its intended medical purposes, and not being sold to youth. Additionally, with better dosing prescriptions, medical marijuana does not have to become defacto marijuana legalization. Doctors can ensure that only the amount of marijuana needed is being prescribed to a patient.

DUID (Driving under the influence of drugs)

Data for marijuana DUIDs are very noisy, making it difficult to draw conclusions about the effects of legalization. Newly legalized states implemented new DUID laws and added resources for enforcement simultaneously with implementing legalized marijuana. Because there are new laws and increased enforcement, it is not advisable to compare post-legalization data with pre-legalization data. In Colorado, from 2013 to 2015, the percentage of drivers involved in fatal accidents who tested positive for THC increased from 11% to 18%.⁴ These data appear to show a trend of more drivers involved in fatal accidents testing positive for THC over time. However, a positive test for cannabinoids may be the result of active THC or one of its inactive metabolites and does not necessarily indicate impairment. Furthermore, more years of data are needed. Still, it is a statistic that should be monitored closely over time.

Recent studies are conflicted over whether legalization has caused an increase in traffic accidents and fatalities. The American Journal of Public Health found a decrease in marijuana-related traffic accidents in states with legal medical marijuana, while a study from the Insurance Institute for Highway Safety found the states with legalized (adult-use) marijuana saw a slight increase. A third study, also in the American Journal of Public Health found no increase in Colorado and Washington when compared to similar states that had not legalized. Regardless of the effects of legalization, it is indisputable that driving while high is dangerous.

Monitoring and enforcing DUIDs is complicated. First, there is no established test similar to a breathalyzer that is currently valid for approximating THC levels in the blood. There are several in development, but the research is still being established. The driver must be taken to a lab or

⁴ Source: Data provided by Colorado Department of Transportation, 8/4/2016.



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police department where blood is drawn and tested. Additionally, THC does not leave the bloodstream in a uniform manner. Active THC dissipates within 5 hours, but for chronic users it may continue to be present for weeks or even months, even if the individual is not impaired. Finally, we do not have the science to date to know if the presence of THC in the blood is as clear of a sign of impairment as alcohol. Thus, states are all forming different standards for intoxication.

Utilizing Vyripharm's imaging technology to better understand marijuana intoxication and to help create roadside sobriety tests: We need to accelerate our understanding of marijuana impairment over time. With Vyripharm's technology, we could track the effect of marijuana on the brain and body at separate points after ingestion. Additionally, we could analyze THC levels in the blood and breath at those times to create and validate roadside sobriety tests.

Medical Usefulness

Even with the severely restricted ability to research the medicinal uses of marijuana, the research Vyripharm has completed to date has yielded positive initial results in the use of cannabinoids in applications for neurologic disorders including, but not limited to, post-traumatic stress disorder ("PTSD") epilepsy, metabolic disorders, and cancers. Vyripharm has already been accepted to present these findings at highly respected scientific conferences:

- To be presented at the 2nd Annual Summit for Cell Metabolism: Oncomine Gene Expression Profiling of the Endocannabinoid Receptors Expressed in Cancer Cells: Non-Hodgkin Lymphoma (NHL), being the most common hematological malignancy, accounts for ~500,000 lymphoma patients annually and attributes to ~20,000 lymphoma-related deaths. B-cell lymphoma makes up 85% of NHL where the most common is diffuse large B-cell lymphoma (DLBCL) and one of the more aggressive forms is mantle cell lymphoma (MCL). There are putative targets for therapy where the current investigation seeks to discover if there is a significant role of the endocannabinoid receptors in cancer cells, particularly lymphomas. This study required primary DLBCL cell lines isolated from patient samples for testing for CB1 and CB2 mRNA expression; where isolated cells from patient samples were obtained through a protocol approved by the Institutional Review Board at MD Anderson Cancer Center. Oncomine gene expression profiling results demonstrated that lymphoma, compared to other tumor types had the highest over-expression of CB1



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receptors, with CNS cancers and gastric cancers close behind. In several independent studies, MCL has been shown to express higher levels of CB1 and CB2 than in reactive lymphoid tissue or purified B cell subsets representing various stages of B cell differentiation (Wasik, 2015). With this information, we decided to investigate CB1 and CB2 mRNA expression in Diffuse Large B-cell Lymphoma cell lines. Western blotting assay results confirmed high mRNA expression levels of CB1, thus deeming CB1 as a potential therapeutic target.

- To be presented at the 2nd Annual Summit on Cell Signaling and Cancer Therapy: Endocannabinoid System Activates Cell Death: Non-Hodgkin Lymphoma (NHL), being the most common hematological malignancy, accounts for ~500,000 lymphoma patients annually and attributes to ~20,000 lymphoma-related deaths. B-cell lymphoma makes up 85% of NHL where the most common is diffuse large B-cell lymphoma (DLBCL). Based on previous studies the endocannabinoid system potentially plays a significant role in lymphoma cells; where CB1 overexpression has been demonstrated. Our current investigation seeks to discover if a CB1 antagonist can induce apoptosis, particularly in DLBCL. Our study takes cells from DLBCL cell lines (McA and LY-19), plating them at 5,000 cells per plate. The cells were incubated 24 and 48 hours in 20 μ L medium with 10% FBS and varied concentrations (0.63, 12.5, 25 and 50 μ M) of Rimonabant (CB1 antagonist) or dimethylsulfoxide (DMSO) vehicle. Apoptosis assays were performed using Annexin V/PI staining followed by flow cytometry analysis. As a result, apoptotic studies done with DLBCL cell lines demonstrated that Rimonabant at concentrations of 50 μ M induces >50% apoptosis in McA cell lines and >80% in LY-19 cell lines.
- To be presented at the 4th Annual Conference on Preventive Oncology: Targeting Cannabinoid Receptors for Cancer Treatment: Non-Hodgkin Lymphoma (NHL), being the most common hematological malignancy, has long been studied where the most common is diffuse large B-cell lymphoma (DLBCL) and one of the more aggressive forms is mantle cell lymphoma (MCL). Previous studies demonstrated that lymphomas not only express CB2 receptors, which are known to be associated with immune cells, but over express CB1 receptors. Therefore the aim of this study is to investigate how various cannabinoid compounds affect DLBCL and MCL cell lines. Methods included cells from representative



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DLBCL and MCL cell lines being plated at 5,000 cells per well. The cells were incubated for 72 hours in 20 μ L medium with 10% FBS and treated at varied concentrations of SR141716-CB1 antagonist (Rimonabant), CP945598-CB1 antagonist (Otenabant), AM251-CB1 inverse agonist, AM1241-CB2 agonist, or dimethylsulfoxide (DMSO) vehicle. Viability assays were then conducted using Celltiter-Glo Luminescent Cell Viability Assay. Experiments were performed 2-3 times independently with each concentration tested in triplicate. The studies included dose dependent viability studies conducted with following cannabinoids: SR141716, a CB1 antagonist (Rimonabant), CP945598, a CB-1 antagonist (Otenabant), AM251, a CB-1 inverse agonist, and AM1241 a CB-2 agonist. All drugs showed a reduction in viability, with most drugs exerting an effect at a concentration of 10 μ M or more with 0% of control at concentrations of 100 μ M.

- To be presented at the 20th World Congress on Pediatric Oncology and Nursing: Effect of CBD Extract on Malignant Lymphoblastic Disease: Diffuse large B-cell lymphoma (DLBCL) and mantle cell lymphoma (MCL) represent the most common and most aggressive forms of Non-Hodgkin lymphoma (NHL) respectively. Previous work has demonstrated CB1 antagonists as potential therapeutics for both DLBCL and MCL. Cannabidiol (CBD) is a natural cannabinoid analog that has mixed affinity across CB1 and CB2 receptors; known in the literature as a CB1 antagonist. Our previous work has demonstrated that CB1 antagonists has activity against DLBCL cell lines. Our study is aimed at demonstrating whether CBD has activity in DLBCL and MCL cell lines. Cells from representative DLBCL and MCL cell lines were plated at 5,000 cells per well. The cells were incubated for 72 hours in 20 μ L medium with 10% FBS and varied concentrations of CBD oil or dimethylsulfoxide (DMSO). Viability assays were conducted using Celltiter-Glo Luminescent Cell Viability Assay. Experiments were performed 2-3 times independently, and each concentration was tested in triplicate. CBD oil effectiveness was demonstrated via viability studies comparing it with CBD-99 CB2 agonist on both DLBCL and MCL cell lines. The data is consistent showing a marked decrease in viability at concentrations of 20 μ M or greater. In MCL and DLBCL cell lines treated with CBD oil, cells reach 0% of control at 50 μ M. Most MCL and DLBCL cell lines treated with CBD-99 CB2 agonist reach 0% of control at concentrations of 100 μ M with many at 0% of control at 50 μ M.
- To be presented at the 28th International Conference on Cancer Research and Anticancer Therapy: An Integrative Approach with Cannabinoid Analogues: Non-Hodgkin Lymphoma



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(NHL) is the most common hematological malignancy, with an aggressive form mantle cell lymphoma (MCL). Previous studies demonstrated that lymphomas over express CB1 receptors; as well as cannabinoid analogs showing therapeutic promise. The aim of this study is to investigate how various cannabinoid compounds can integrate with traditional chemotherapeutics in MCL cell lines. Our method includes harvested cells from representative MCL cell lines being plated at 5,000 cells per well. The cells were incubated for 72 hours in 20 μ L medium with 10% FBS and varied concentrations of Ibrutinib (IBN), Venetoclax (ABT-199), Rimonabant (SR141716), or dimethylsulfoxide (DMSO) vehicle. Viability assays were conducted using Celltiter-Glo Luminescent Cell Viability Assay with experiments performed 2-3 times independently with each concentration tested in triplicate. Drug synergy viability studies were conducted to compare effectiveness among conventional treatment of IBN, ABT-199 and SR141716, a CB1 antagonist, in various combinations. Data suggest the most effective combination being IBN and ABT-199, showing lowest concentration of 6.5 μ M for cells to be at 0% of control. However, results with CB1 antagonist proved to be effective in the combination of ABT-199 and SR141716; showing less than 12.5% of control at concentrations of 6.5 μ M. Other drug combinations and individual drugs were less effective showing a 0% of control at concentrations of 12.5 μ M and greater. Reduction in viability is shown to be greater among combinations of drugs as opposed to individual effect of a single drug, depicting synergistic efficacy.

- To be presented at The American Society of Clinical Oncology: Drug effectiveness of compound VYR-206 was compared to CB1 antagonist Rimonabant with N4 as a control in both DLBCL and MCL cell lines. Drug VYR-206 follows closely to Rimonabant in VYR-206 sensitive DLBCL cell lines with reduction of viability at concentrations <100 μ M and 0% of control at 200 μ M. In VYR-206 resistant DLBCL cell lines reduction of viability occurs at concentration of 100 μ M or more, still with 0% of control occurring at 200 μ M. Drug VYR-206 appears to show more effectiveness in VYR-206 sensitive MCL cell lines, showing a reduction in viability at concentrations <50 μ M with 0% of control at 100 μ M. In VYR-206 resistant MCL cell line Rec-1, drug VYR-206 fails to decrease viability below 50% of control even at concentrations of 400 μ M. Conclusions: VYR-206 has the potential for both the treatment and assessment of the efficacy of cannabinoid therapy in malignant lymphoma cancer.



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- To be presented at the Conference on Cellular Therapies: CBD Efficacy in Human DLBCL and MCL: Diffuse large B-cell lymphoma (DLBCL) and mantle cell lymphoma (MCL) represent the most common and most aggressive forms of Non-Hodgkin lymphoma (NHL) respectively; where DLBCL are characterized in two gene expressing groups: germinal center B-Cell-like (GCB) and aggressive activated B-cell like (ABC). Previous work has demonstrated CB1 antagonists as potential therapeutics for both DLBCL and MCL. Cannabidiol (CBD) is a natural cannabinoid analog that has mixed affinity across CB1 and CB2 receptors; known in the literature as a CB1 antagonist. Our previous work has demonstrated that CB1 antagonists has activity against DLBCL cell lines. Our study is aimed at demonstrating whether CBD has activity in DLBCL and MCL cell lines. Cells from representative DLBCL and MCL cell lines were plated at 5,000 cells per well. The cells were incubated for 72 hours in 20 μ L medium with 10% FBS and varied concentrations of CBD or dimethylsulfoxide (DMSO) vehicle. Viability assays were conducted using Celltiter-Glo Luminescent Cell Viability Assay. Experiments were performed 2-3 times independently with each concentration tested in triplicate. In vitro studies were done to determine efficacy of CBD in DLBCL (GCB and ABC), as well as MCL. GCB-DLBCL, aggressive ABC-DLBCL and MCL cell lines treated with CBD showed similar patterns of reduction in viability. Most cell lines dropped dramatically in viability at concentrations of 10 μ M or greater with most cell lines at 0% of control at concentrations of 50 μ M.
- To be presented at the International Conference on Pharmaceutical Research and Development: Comparing Novel Cannabinoid Analogues vs Known Cannabinoid Analogues: Diffuse large B-cell lymphoma (DLBCL) and mantle cell lymphoma (MCL) represent the most common and most aggressive forms of Non-Hodgkin lymphoma (NHL) respectively. Previous work has demonstrated CB1 antagonists as potential therapeutics for both DLBCL and MCL. Our drug formulation VYR-206 was developed from existing obesity treatment Rimonabant, a CB1 antagonist, by the addition of our tetraazacyclic (N4) conjugate derivative, allowing the potential for image guided theranostic application for diagnosis, precision and assessment of therapeutic response through radiotracer chelation. Our study aims at comparing our novel conjugate formulation VYR-206 activity in DLBCL and MCL cell lines to its precursor Rimonabant. Cells from representative DLBCL and MCL cell lines were plated at 5,000 cells per well. The cells were incubated for 72 hours in 20 μ L medium with 10% FBS and varied concentrations of experimental cannabinoid antagonist VYR-206, Rimonabant, or dimethylsulfoxide (DMSO) vehicle.



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Viability assays were conducted using Celltiter-Glo Luminescent Cell Viability Assay. Experiments were performed 2-3 times independently, with concentration tested in triplicate. Data shows nearly overlapping curves in most cell lines for both DLBCL and MCL, with viability reduction at approximately 30 μ M and 0% of control at 100 μ M for both drugs. Cell lines identified as CJ and TMD-8 from DLBCL showed a reduced response to VYR-206, with viability unable to fall below 100% of control in the previous data. MCL cell lines identified as JMP-1 and Rec-1 failed to decrease viability pass 75% at concentrations of 100 μ M in previous data.

- To be presented at the Society of Nuclear Medicine and Molecular Imaging Conference: Biodistribution studies demonstrated that Tc-99m-VY206 showed up in the brain and gut. The brain and gut uptake could be clearly visualized by Tc-99m-VY206. It was noted that the brain had high uptake in a rat model using Tc-99m-VY206, suggesting decarboxylation might have been occurred. Conclusions: Tc-99m-VY206 has a potential for the assessment of the efficacy of cannabinoid therapy in many disease states.

It should be beyond dispute that enough evidence exists today to prove that marijuana has many effective medical uses. Vyripharm's initial studies are already being widely accepted in the medical community. With a rescheduling of marijuana, Vyripharm could fast track these studies and help provide the United States and the world with useful applications for neurologic disorders including, but not limited to, post-traumatic stress disorder ("PTSD") epilepsy, metabolic disorders, and cancers.

Preventing Diversion

One of the most difficult dynamics for allowing for less restrictive marijuana research is that there is the possibility it will create a supply of significantly less expensive marijuana. The worry is that if the price of wholesale medical marijuana is significantly lower than black market marijuana, bad actors will attempt to divert medical marijuana to the black market.⁵ This dynamic has been seen in states with legalized marijuana. These abuses can range from small-scale operations (e.g., a purchaser buying the legal limit at a retail store and driving across the border to sell) to large-scale operations (e.g., a growing and distribution operation that is

⁵ <http://www.greenstate.com/explainers/a9551472/foolish-fallacies-eliminating-the-black-market-overnight>



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shipping hundreds of pounds of marijuana).⁶ While all out-of-state diversion is problematic, large-scale illegal operations are often accompanied by violence,⁷ property destruction,⁸ and environmental destruction.⁹

While it can be hard to measure the size of this problem, there is ample evidence that strong accountability systems can prevent large scale diversion.¹⁰ In Colorado, for example, nearly all of the enforcement actions for out of state diversion emanated from the home grow market, which does not require seed-to-sale tracking. Inside the regulated system, the state-mandated inventory tracking system requires that every plant be tagged with a radio frequency identifier. If the federal government were to require similar systems, such as Vyripharm’s cloud-based block-chain data platform, we could ensure the integrity of the supply-side and be able to track and prevent any diversion. In fact, since 29 states and Washington DC already have medical marijuana, a federal mandate that all of these systems utilize such technologies would probably do significantly more to prevent diversion than the status quo. In short, the federal government

⁶ More than 40 people were arrested and approximately 30 Denver-area homes and warehouses were raided as part of an extensive law enforcement action conducted in one day in April 2016. All the raids are tied to one illegal operation. The suspects allegedly came from Texas to grow marijuana in Colorado. At one home in Centennial, agents found more than 300 plants. There was so much grow equipment at the home that a National Guard truck was called in to haul it away. In another location, a person barricaded himself inside a building that was raided. Police were forced to use tear gas to extract him—*Denver CBS 4, May 6, 2016*

⁷ Keith Hammock of Denver shot two teenage boys who were attempting to steal marijuana plants from a large grow at Hammock’s home. Fifteen-year-old Keylin Mosley was killed and the other 14-year-old boy was paralyzed—*Denver Post, October 10, 2016*

⁸ Jon Didleaux’s tenant was caught with close to 56 pounds of marijuana in Didleaux’s home. The worst part: Didleaux spent months fixing up his 1,800-square-foot home, only to see it almost destroyed. His insurance company paid \$20,000 to cover the damage to the property—*KKTV 11 News, May 5, 2016*.

⁹ A grass fire in Pueblo West has been linked to an illegal marijuana grow. The 2-acre grass fire started when a transformer had blown because a home was pulling too much electricity. Deputies noticed a strong marijuana odor coming from the home and found a partial medical marijuana license. The home was set up with a commercial heating and ventilation system along with extensive lighting and irrigation systems. Authorities found 49 budding plants and another 117 freshly harvested plants in the home—*Colorado Springs Gazette, April 21, 2016*

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<https://legislature.vermont.gov/assets/Documents/2016/WorkGroups/Corrections%20Oversight/Marijuana%20Legalization/W~Andrew%20Freedman~Marijuana%20Grey%20Market%20-%20Colorado%20Office%20of%20the%20Governor~9-12-2016.pdf>



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would be in a position to promote and require anti-diversion technology that would better protect public safety.

Conclusion

We are concerned that as states take on more liberal laws, and as people start to view marijuana more favorably, there is not enough research being conducted to determine both positive medical uses and negative public health consequences. Without this research, individuals and states are making decisions based on anecdotal evidence alone. We believe that a shift in federal policy to allow for responsible research will significantly aid public well-being. Additionally, if done correctly, better controlling the medical marijuana supply chain will lead to significantly less diversion. We strongly urge you to reevaluate our current medical marijuana policies and reschedule this drug.

About us:

Dr. Jerry Bryant, Jr., Chief Scientist Officer and Managing Member/Board Member

Focus and outline company's strategies and executions in setting priorities for comprehension testing, pharmaceutical product development and transition to clinical Proof of Concept stage. This entails outlining regulatory standards for new drugs and assist in company's operations. Bryant currently is a Co-founder of a biotechnology company that is presently valued at over \$100MM. After graduate school, Bryant spent over 12 years at UT MD Anderson Cancer Center in Houston, TX and has presented/published extensively. Bryant has a deep and extensive hands-on research experience in cardiovascular, microbiology and oncology all at the molecular level. He has several patents from his work and is working on several more. In addition, he has a vast business background and completing medical school. His vast experience in research, medicine and biotechnology has provided the company with realistic time lines to explore and validate new drugs that will translate into lowering the cost from concept to clinic and better outcomes in the clinical setting.

Andrew Freedman, Andrew Freedman is co-founder and Senior Director of Freedman & Koski, Inc. Andrew's first-in-the-nation consulting firm works with government, research institutions, communities and private businesses to get cannabis legalization right. Andrew brings vast



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experience from his three years as the State of Colorado's first Director of Marijuana Coordination. During this time, he developed distinctive experience effectively implementing voter-mandated legalized recreational and medical marijuana while protecting public health, maintaining public safety, and keeping marijuana out of the hands of children.

Andrew's role in developing a successful operating model for cannabis regulation and stakeholder collaboration was identified as one of the reasons for the State of Colorado's success in implementing recreational marijuana legalizations by the Brookings Institution. Governor Hickenlooper has gone so far as to praise Andrew's work while on national television, stating, "Andrew Freedman, who came in and helped us once it was passed . . . [has] done a remarkable job of creating a regulatory framework."

Andrew joined Hickenlooper's gubernatorial campaign in 2010 and was tapped to be Chief of Staff for Lieutenant Governor Joe Garcia. In 2013, Andrew became the director of Colorado Commits to Kids, the largest effort to-date to overhaul Colorado's education funding system, before being appointed as Colorado's Director of Marijuana Coordination.

Andrew has received national recognition for his leadership. He was recognized as one of Fast Company's "100 Most Creative People in Business" in 2016 and featured on 60 Minutes, NBC Nightly News, The Today Show, The New York Times, The Washington Post, The Wall Street Journal, The Boston Globe, Governing Magazine, and dozens of local stories throughout the nation and internationally.

Andrew holds a J.D. from Harvard Law School and a B.A. in philosophy and political science from Tufts University.

Lewis Koski

Lewis Koski was the Director of the Colorado Marijuana Enforcement Division during the legalization of marijuana. Lewis played a pivotal role building the first agency in the world to implement medical and retail marijuana policy, constructing innovative strategies to develop balanced regulations, launching the first marijuana inventory tracking system and finding solutions to some of the biggest challenges the State faced developing and implementing divisive mandates related to contemporary marijuana laws.



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Lewis is recognized nationally and internationally as an expert in formative marijuana policy. He is among a small group of government executives who have been intimately involved in the development and implementation of marijuana policy from the infancy of medical marijuana through the realization of legalization. Lewis' leadership contributions and devotion to implementing marijuana policy thoughtfully played an important role achieving what has become one of the most fully developed marijuana regulatory frameworks in the world.

Lewis holds a Master of Business Administration with an emphasis on International Business and is a Doctoral Candidate in Public Administration with a focus on policy analysis and public participation in rulemaking.

About Vyripharm:

Vyripharm Enterprises LLC is a privately held biopharmaceutical company. The Company has established two divisions, one a proprietary comprehensive analytical testing, monitoring, tracking and genomic system that we feel will be embraced as the standard accepted methodology to help create stability and predictability in the emerging business of medical cannabis and the second one is a Life Sciences Precision Medicine Platforms. These Platforms that the company have in its portfolio from tradition Pharmaceutical proof of concept developments will be integrated to develop novel applications for medical cannabinoids (using in-licensed proprietary technologies in combination with cannabinoids) in nuclear medicine and therapeutic applications for neurologic disorders including, but not limited to, post-traumatic stress disorder ("PTSD") epilepsy, metabolic disorders, and cancers.

Vyripharm's mission is to establish an ethical, pharmaceutical business model that transcend and integrate non-traditional medicine (medical cannabinoids, etc.) with traditional medicine (pharmaceutical medicines) that will improve the lives of patients in our global community. Vyripharm's innovative approach by integrating IT and Precision Medicine Platforms, integrity and dedication to patient welfare, will be the new standard of the 21st century biopharmaceutical company.