SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF ALBANY

CANNABIS IMPACT PREVENTION COALITION, LLC.; CANNABIS INDUSTRY VICTIMS SEEKING JUSTICE, LLC.; RENNE BARCHITTA; EDWIN DE LA CRUZ; ERIC R. DE LA CRUZ; PHIL ORENSTEIN; PHILIP MCMANUS; ROBERT CAEMMERER; RICHARD P. MCARTHUR; RONNIE HICKEY AND JOHN AND JANE DOES 1-15 AND XYZ CORPORATIONS 1-15, JOINTLY Petitioners -against- KATHY HOCHUL, GOVERNOR OF NEW YORK, IN HER OFFICIAL CAPACITY; NEW YORK STATE CANNABIS CONTROL BOARD; NEW YORK STATE OFFICE OF CANNABIS MANAGEMENT; TREMAINE WRIGHT CHAIRWOMAN OF THE NEW YORK STATE CANNABIS CONTROL BOARD IN HER OFFICIAL CAPACITY; AND CHRISTOPHER ALEXANDER EXECUTIVE DIRECTOR OF THE NEW YORK STATE OFFICE OF CANNABIS MANAGEMENT, IN HIS OFFICIAL CAPACITY; JOHN AND JANE DOES 1-15 AND XYZ CORPORATIONS 1-15, JOINTLY Defendant-Respondents	Index No. VERIFIED PETITION ORAL ARGUMENT REQUESTED

Petitioners by and through their undersigned counsel, hereby commence this hybrid Article 78 and declaratory judgment proceeding, pursuant to New York Civil Practice Rules and Procedure ("CPLR") §§ 7803(1), 7803(2), and 3001 against Respondents KATHY HOCHUL Governor of New York in her official capacity, the NEW YORK STATE CANNABIS CONTROL BOARD ("CCB"), the NEW YORK STATE OFFICE OF CANNABIS

MANAGEMENT ("OCM"), TREMAINE WRIGHT, in her official capacity as Chairwoman of the New York 'State Cannabis Control Board, and CHRISTOPHER ALEXANDER, in his official capacity as Executive Director of the New York State Office of Cannabis Management (collectively the "Respondents").

The statements and facts herein are based on information and belief.

PRELIMINARY STATEMENT

1. The New York Legislature enacted the Marihuana Regulation and Taxation Act ("the MRTA" aka "the Cannabis Law") on March 31, 2021. The statute legalized cannabis products for adult-use, and established an Office of Cannabis Management (OCM) as an independent agency within the Division of Alcoholic Beverage Control to regulate the cannabis marketplace, and entrusted the OCM and the Cannabis Control Board (CCB) (its oversight board) with launching New York's adult-use cannabis industry. McKinney's Cannabis Law 2.

2. MRTA refers to products made from the dried leaves and flowers of the cannabis plant as "marihuana." Since federal law uses the term "marijuana," that term will be used herein and refers to all cannabis products in New York. [1]

3. After the MRTA was effective, the Respondents promulgated the following rules:

a. Medical Cannabis, 9 NYCRR 113 adopted 2/22/23

b. Adult-Use Packaging and Labeling, 9 NYCRR 128 adopted 3/22/2023

c. Adult-Use Marketing and Advertising, 9 NYCRR 129 adopted 3/22/2023

d. Cannabis Laboratories 9 NYCRR 130 adopted 3/22/2023 [2]

4. By this Petition Petitioners challenge the below rules:

a. Medical Cannabis, 9 NYCRR 113 adopted 2/22/23

b. Adult-Use Packaging and Labeling, 9 NYCRR 128 adopted 3/22/2023

c. Adult-Use Marketing and Advertising, 9 NYCRR 129 adopted 3/22/2023

5. Respondents are attempting to orchestrate a marijuana trafficking operation utilizing taxpayer funds and public employees and resources. Their blatant disregard of every major objective embodied in federal marijuana law directly conflicts with, and otherwise stands as an obstacle to, Congress's mandate that production, possession and distribution of Schedule I drugs, including marijuana, be prohibited unless approved by federal law. This prohibition embodies not just the considered judgment of Congress, but also the United States international treaty obligations that have been ratified by the United States (and relied upon by other countries who are similarly obligated). [3] The 1961 Single Convention on Narcotic Drugs ("Single Convention") requires signatories to prohibit the recreational use of cannabis within their territories. [4] The United States is a signatory to this treaty, which was ratified by the United States Senate and entered into force on June 24, 1967. [5] The 1970 Controlled Substances Act, Title 21, United States Code, Sect. 801 et seq. prohibits the production, sale and possession of marijuana as a Schedule I controlled substance in the United States.[6]

6. This hybrid Article 78 and declaratory judgment proceeding seeks to put an end to Respondents' unconstitutional *ultra vires* venture into rule making in violation of federal law and to compel CCB and OCM to perform their executive duties in accordance with federal law.

7. The scientific evidence will show that Marijuana is capable of wreaking havoc on the health, safety, economic strength and cognitive function of our nation's citizens. Yet, for no other drug is the gap so large between current scientific evidence of adverse consequences and

the public perception. The marijuana lobby has engaged in a well-funded campaign to spread false information. They put profits before people. Our children are paying the price. The Petitioners depend on the outcome of this litigation, since it is the most likely way to bring these significant points of law before the courts.

8. The MRTA legalized marijuana cannabis for adult-use and established OCM as an independent agency within the Division of Alcoholic Beverage Control, and entrusted OCM (and CCB, the entity that oversees OCM) with, inter alia, (i) launching New York's adult-use cannabis program; (ii) creating a safe, licensed, and regulated cannabis industry; (iii) generating sufficient tax revenue through cannabis sales to re-invest in communities disproportionately harmed by federal and state drug policies; and (iv) "reducing the illegal drug market ... and reduc[ing] the participation of otherwise law-abiding citizens in the illicit market. (Emphasis added).

9. CCB and OCM have improperly assumed the role of the U.S. Congress and the federal Drug Enforcement Administration (DEA) and the Food and Drug Administration (FDA) to impose their own policies and judgment over those federal agencies that are far better experienced and qualified to do so.

10. Respondents' arbitrary and capricious foray into rule making will harm the citizens of New York for whom the Petitioners support and advocate for.

11. The United States Court for the Northern District of New York has already issued a preliminary injunction under the Commerce Clause enjoining a portion of Respondents' plan because the program will have a discriminatory effect on out-of-state residents seeking a

Conditional Adult-use Retail Dispensary (CAURD) license. Variscite NY One v New York 1 22 cv 1013 (GLS/DJS) 2022 WL 17257900 at *19 (N.D.N.Y. Nov. 10, 2022).

THE PARTIES

12. Petitioner Cannabis Impact Prevention Coalition, LLC. (CICP) is a corporation organized under the laws of the State of New York. The mission of CIPC is to prevent the social, health, public safety and environmental impacts of marijuana. CIPC has taxpayer and resident members in New York who are not listed as Petitioners and some who are.

13. Cannabis Industry Victims Seeking Justice (CIVSJ), is a corporation organized under the laws of the State of New York. CIVSJ provides advocacy services to the many victims of the cannabis industry. CIVSJ's mission is to make the marijuana industry legally accountable to their victims. CIVSJ has taxpayer members in New York who are not listed as Petitioners and some who are. Federal law recognizes victims of criminal activity 18 U.S.C. 3663.

14. Plaintiff-Petitioner Phil Orenstein, is a New York taxpayer and resident and member of CIPC who has had devastating personal experiences with marijuana and is a former teacher in a drug prevention and motivational program in NYC public schools.

15. Petitioner Edwin De La Cruz, is a New York taxpayer and resident and member of CIVSJ and CIPC, and is a father concerned about the damage caused by his son's consumption of marijuana.

16. Petitioner Eric R De La Cruz, the son of Edwin De La Cruz, has sufferance from consumption of marijuana.

17. Renee' Barchitta is a New York taxpayer and resident and a member of CIVSJ

and CIPC. She is a former Delaware County (NY) STOP-DWI Educator/Coordinator, Highway Safety Representative for the NYS Governor's Traffic Safety Committee.

18. Petitioner Philip McManus, is a New York taxpayer and resident and member of CIVSJ and CIPC.

19. Petitioner Robert Caemmerer, is a New York taxpayer and resident and member of CIVSJ and CIPC.

20. Petitioner Richard P. McArthur is a New York taxpayer and resident and member of CIPC.

21. Petitioner Ronnie Hickey is a New York taxpayer and resident and member of CIPC and has sufferance from marijuana smoke in her apartment building.

22. CIVSJ was created to help families who have lost loved ones due to marijuana related mental illness, physical illness and automobile crashes. CIVSJ counsels parents whose children have developed an addiction to marijuana or become mentally ill or are harmed in some other way by marijuana.

23. CIVSJ is the New York division of Cannabis Industry Victims Educating Litigators (CIVEL). CIVEL was incorporated in New Jersey in 2018 and has sought to educate litigators and legislators nationally on how to protect the many victims of the marijuana industry. CIVEL has published articles on the damage caused by the marijuana industry.

24. CIVEL had organizational standing in Botteon v. Murphy, a New Jersey case brought by CIVEL concerning federal law preemption and the state marijuana law. NJ Superior Court MID-L-002293 (2020).

25. CIVEL did an undercover investigation on behalf of a person who had cancer and

went to a New York marijuana doctor who was then violating the states' rules and federal law about medical use of marijuana. In addition, CIVEL has been active in New York by submitting comments on the proposed rules that are in question here. (Exhibit 1)

26. CIVSJ and CIPC are organizations concerned with the care and protection of children abused by parents due to parental marijuana use who would be unable to seek a judicial remedy. It is not likely that their parents or caretakers, the objects of the abuse claims, would do so.

27. Petitioners have an active interest in the outcome of this controversy and not a mere casual interest in the problem presented in the suit. Both CIVSJ and CIPC were organized around the concerns of those damaged by the marijuana industry and the Respondents.

28. CIVSJ and CIPC represent the victims of the marijuana industry who have been, are being, or will actually be harmed by the challenged actions. As marijuana industry victims' advocacy organizations, CIVSJ and CIPC have a direct and particularized interest in federal and state law regarding marijuana in all of its forms. The legalization of marijuana by a state is in conflict with federal law and impedes the efforts of CIVSJ and CIPC to gain the protection of federal and state law for the many victims of the marijuana industry. The concerns of CIVSJ and CIPC are not too "generalized" for standing purposes and are not abstract and indefinite in nature. U.S. Const. art. 3, 2, cl. 1; Comprehensive Drug Abuse Prevention and Control Act of 1970 101, 21 U.S.C. 801 et seq. Sisley v. DEA, 11 F.4th 1029 (CA (2021).

29. The categories of the victims of the marijuana industry that CIPC and CIVSJ seeks to protect include:

Accident victims.
Abused elders
Unborn children and nursing babies

Children of marijuana users
Crime victims
Domestic violence victims
Drug Dealer Liability Act victims
Employers
Environmental victims - Many people suffer damage due to pollution from marijuana growing operations and marijuana smoke.
Parents and grandparents
Marijuana consumers
Marijuana addicts
Marijuana intoxicated driving victims
"Medical" marijuana users
People who suffer mental health impairment due to marijuana
Property owners
Sexual victims
Students and schools
Trademark and copyright infringement
Workers and farm employees in the marijuana industry
Those threatened and harassed by marijuana users and marijuana advocates.
The public
For more information on the categories of victims go to www.civel.org

30. CIVSJ and CIPC have third-party standing to maintain an action.

31. The questions involved do not lack justiciability and do not seek the adjudication of moot issues.

32. The Petitioners have a special interest to be served or some particular right to be preserved or protected over and above the interest held in common by or with the public at large.

33. These concerns are concrete and actual and neither conjectural or hypothetical.

34. This matter affects substantial segments of the population, and its outcome will have a direct bearing on commerce and finance and industry, or agriculture, generally.

35. Petitioners raise issues of great public importance involving clear threats to the essential nature of state and federal government guaranteed to citizens under their constitution

36. Defendant Kathy Hochul is the Governor of New York a U.S. State.

37. Respondent New York State Cannabis Control Board ("CCB") is a government-appointed board that the MRTA established to promulgate rules and regulations for New York's cannabis industry and vested with the powers and duties stipulated in MRTA § 10. It consists of a chairperson and four other voting members.

38. Defendant-Respondent Tremaine Wright is, and was, at all times relevant to this action the Chairwoman of CCB, having the powers and duties granted to her, and she is named in her official capacity.

39. Defendant-Respondent New York State Office of Cannabis Management ("OCM") is an independent office that the MRTA established within the Division of Alcoholic Beverage Control.

40. Defendant-Respondent Christopher Alexander is, and was, at all times relevant to this action the Executive Director of OCM, having the powers and duties granted to him in his official capacity, and he is named in his official capacity.

41. The attempt of a State officer to enforce an unconstitutional law is an illegal act, and the officer is stripped of his official character and is subject in his person at capacity to the consequences of his individual conduct.

42. The State has no power to provide its officer with immunity from responsibility to the supreme authority of the United States. Ex Parte Young, 209 U.S. 123 (1908)

JURISDICTION AND VENUE

43. This Court has subject matter jurisdiction to decide this Verified Petition pursuant to CPLR §7803 because (i) CCB and/or OCM have failed to perform a duty the federal law requires of them and/or is proceeding in excess of jurisdiction, and (ii) Respondents' rules

adopted in February and March of 2023 governing the medical cannabis program and labeling and advertising are final determinations which are arbitrary and capricious, violations of lawful procedure, and/or affected by errors of law. This Court also has jurisdiction to render a declaratory judgment pursuant to CPLR § 3001. Venue lies in Albany County pursuant to CPLR §§ 506(b) and 7804(b) because upon information and belief, OCM's and CCB's principal offices are located in Albany, New York and it is where Respondents failed to perform their legal duties and/or where the material events giving rise to Petitioner's suit took place.

44. The Court has personal jurisdiction over the OCM and CCB because they are offices of the state.

45. The Court has personal jurisdiction over Tremaine Wright because, on information and belief, she is a domiciliary of New York and she took the actions complained of herein while in New York.

46. The Court has personal jurisdiction over Christopher Alexander because, on information and belief, he is a domiciliary of New York and he took the actions complained of herein while in New York.

47. Venue is proper in this Judicial District because on information and belief, OCM is a division of the State of New York, the laws and regulations challenged herein were passed in Albany, and Respondents performed the actions complained of herein while within this Judicial District.

48. This Court is authorized to grant the declaratory relief requested pursuant to New York CPLR 3001 and 28 U.S.C. 2201.

49. This Court is the proper venue for this proceeding pursuant to New York CPLR

504 (3) and CPLR 7804 (b), because Petitioners are residents and taxpayers in New York.

RELEVANT FACTS

50. Marijuana is a derivative of the cannabis plant as are other products such the various forms of tetrahydrocannabinol (THC) and cannabidiol (CBD). All marijuana/cannabis products to be used as medicines or food or dietary supplement are regulated and controlled pursuant to the federal Controlled Substances Act and other federal food and drug laws such as the Food, Drug and Cosmetic Act (FDCA).

51. Under federal law, marijuana is contraband for any purpose, including for medical purposes. Although marijuana may appear to be nominally "legalized" under some state laws, because marijuana is illegal under federal law, individuals cannot lawfully possess marijuana. Where there is a conflict between federal and state law with respect to the legality of marijuana, the Supremacy Clause of the U.S. Constitution unambiguously provides that federal law shall prevail. U.S. Const. art. 6, cl. 2; Gonzales v. Raich, 545 U.S. 1, 29 (2005). Comprehensive Drug Abuse Prevention and Control Act of 1970 § 202, 21 U.S.C.A. § 812(c); US v. Schostag, 895 F.3d 1025 (CA 8 2018).

52. The actions of the state do not protect the public's health, safety, and welfare. One example of how far the Respondents have gone in failing to protect the health and safety of New York's people is their 2023 Mother's Day "twitter" greeting.

> NYS Office of Cannabis Management
> May 12 Mothers across the nation have faced shame for their cannabis consumption, but anyone who knows a mom, knows, it takes more than grace to get through the day. This #MothersDay we want to end the stigma & share some insight. Tell us, how #NYcannabis has helped you in motherhood? [7]

53. The State of New York is advocating the use of marijuana to "help" mothers "get

through the day." Mothers are responsible for the care of their children, some of whom are infants. Attached as Exhibit 2 are examples of how some New York mothers who used marijuana have permitted their children to die. This Mother's Day greeting is grossly irresponsible and shameful coming from a government agency.

54. Petitioners are concerned about their quality of life and property rights. The Petitioners claim that the marijuana stores and other businesses will cause a diminution in their quality of life by having de facto criminal enterprises in their community. Safe Streets Alliance v. Alternative Holistic Healing, 859 F3rd 865 (CA 10 2017).

55. Petitioners are concerned about having marijuana stores or growing operations in their neighborhoods. Marijuana businesses make bad neighbors. They drive away legitimate business customers, emit pungent, foul smoke and odors, attract undesirable visitors, increase criminal activity, increase traffic, and reduce property values. Petitioners bring this suit to vindicate their federal and state property rights and their substantive due process rights under the state and federal constitutions. There is ample documentation of the many adverse effects of marijuana businesses in addition to the violations of federal law and loss of property values. [8]

56. The U.S. Drug Enforcement Administration (DEA) has received many complaints about marijuana stores including:

a. People smoking marijuana outside the distribution facility.
b. An increase in pedestrian and automobile traffic clogging the streets, illegal parking.
c. Public safety concerns.
d. Loss of customers and business in a once quiet neighborhood.
e. An influx of criminal elements into the neighborhoods.
f. Noise, litter, loitering, property damage.
g. The pungent smell of marijuana seeping into neighboring businesses.
h. The smell of marijuana making people ill.
i. Secondary smoking risks.
j. Threats and harassment.
k. Selling items that look like candy that small children could confuse and ingest.

l. Violations of residential zoning laws.
m. Fire hazards
n. A decrease in business and revenue for legitimate neighborhood stores.
o. A decrease in tourist revenues and tourist traffic.
p. A decrease in property values.
q. Adults have been buying marijuana from the marijuana dispensaries and re-selling marijuana to juveniles. [9]

57. Petitioners are also concerned that the proliferation of marijuana via marijuana stores will pose threats to public safety. The Federal Department of Justice Agrees with them.

58. A federal court recently decided that individuals who want to use marijuana could not also possess guns because the physical and mental impairments caused by drug use make it dangerous for users to possess firearms. The opinion is Fried v. Garland, 2022 WL 16731233 (ND FL 2022). The Department of Justice in their attached brief had this to say about marijuana users. (Exhibit 3)

a. Marijuana use "was associated with elevated risky decision-making" and caused "significant deficits" to "executive planning," while adversely affecting "general motor performance, sustained attention, spatial working memory, and response inhibition." Brief pages 29-30.

b. "Marijuana users exhibit impairments on behavioral control, which "may contribute to poor decision-making." Brief page 30.

c. "Marijuana use "may contribute to cognitive impairments in executive functioning," making marijuana users "more likely to make risky judgments" and "exhibit increased impulsive decision-making." Brief page 30 footnote 16.

d. Heavy marijuana users may be particularly prone to poor decision-making. Brief page 30 footnote 16.

e. Marijuana users "demonstrated numerous cognitive deficits" that affected "decision making. Brief page 30 footnote 16.

f. It is beyond dispute that illegal drug users, including marijuana users, are likely as a consequence of that use to experience altered or impaired mental states that affect their judgment and that can lead to irrational or unpredictable behavior. Brief page 31.

g. "Marijuana users with firearms pose a danger comparable to, if not greater than, other groups that have historically been disarmed. For example, "like the mentally ill," drug users "are more likely to have difficulty exercising self-control, making it dangerous for them to possess deadly firearms." Brief page 31

59. The Respondents' promotion of marijuana trafficking is not aligned with the medical facts and the science and is therefore unreasonable, arbitrary, capricious and illegal. Unlike heroin and other opioids, whose risks are widely disseminated by the media and known by the public, the hazards of today's marijuana are both insidious and minimized. Marijuana is capable of wreaking havoc on the health, safety, economic strength and cognitive function of New York's citizens. Yet, for no other drug is the gap so large between current scientific evidence of adverse consequences and the public perception. The gap has been driven by many factors, including major financial investments by the marijuana industry in promoting misinformation about marijuana safety. The gap between science and medical facts compared to the public perception of harms related to marijuana also has been fueled by celebrities who openly promote marijuana use, as well as by a marijuana industry that advertises aggressively and avails itself of social media sites and sympathetic media outlets.

60. Politicians have been disappointing in their lack of leadership on this issue, since

many have absorbed the misinformation without the counterbalancing scientific and medical facts from the bio-medical and addiction treatment community. As a result, the public is uninformed and dangerously complacent.

61. This litigation will document and produce evidence of these many harms. We intend to remind, and if necessary to compel, our government officials to do their duty to safeguard and ensure our rights and those of our children. By this litigation, Petitioners seek to guide New York officials to protect and preserve the health and safety of the residents of New York, especially the health and well-being of the children. See the attached document on the risks of marijuana use. (Exhibit 4).

62. The Respondents may assert that marijuana businesses will be an economic engine for New York but they have no regard for the priority of sound public policy to promote the health, safety, and welfare of the residents of New York. It has been truthfully said that it is easier to build strong children than repair broken adults. This case matters because it has the potential to significantly impact the well-being of the thousands of children in New York as well as the health and safety of all residents for years to come. When this occurs, there is cause for collective societal concern and action.

63. Respondents' actions "normalize" marijuana in New York for teens and children. The perception of harm from marijuana in states that have "legalized" marijuana plummets for teens. They understandably adopt a dangerous mind set of "Why would adults legalize marijuana if it were harmful?" In the course of this litigation Petitioners will show that:

a. Many teens quickly get addicted to today's marijuana.

b. Many teens develop marijuana-induced amotivational syndrome and will struggle to finish high school or college.

c. Teens who get addicted to marijuana will fall far short in securing their future.

d. Teens vape cannabis products in schools.

e. Teens who use marijuana are at risk of developing mental health problems at increasing rates.

64. In states that have (illegally) "legalized" marijuana, the marijuana industry is following the playbook of the tobacco and opiate industries in trying to get our kids addicted to ensure a new generation of customers. They market to young people with flavored cannabis vape cartridges and with potent THC infused into edible cookies, candies, "gummy bears," sodas, brownies and ice cream. Marijuana advertising uses cartoon characters, Santa Claus, and images from popular kids' movies.

65. Recent marijuana products are advertised as 95% “pure” THC concentration and there are now crystalline products that are 99% “pure” THC. [10] These are far greater - and more dangerous - concentrations than the "Woodstock Weed" of years past that was 2-3% THC. Petitioners will present evidence as to the consequences of this high potency marijuana and to Respondents’ cavalier, dismissive and hypocritical attitude towards these issues.

66. There are a number of federal government documents providing some of the abundant science on the many physical and mental health dangers of marijuana use. They include:

a. Denial of Petition To Initiate Proceedings To Reschedule Marijuana, 81 FR 53767-01, 2016 WL 4240243 (F.R.).

b. US Surgeon General's Advisory: Marijuana Use and the Developing Brain. [11]

c. FDA updates and warning letters and DEA prosecutions. [12]

67. Recent science shows that marijuana use exacerbates mental illness and addiction and many other problems. For example, the 2016 United States Surgeon General report on addiction states that marijuana is a serious threat to the physical and mental health of our children and that its use is a major threat to public safety. [13]

68. The American Psychiatric Association reports that current evidence supports, at a minimum, a strong association of marijuana use with the onset of psychiatric disorders. Mental illness leads to crime, homelessness and enormous societal costs. [14]

69. In 2017, the National Academy of Sciences (NAS) landmark report written by top scientists concluded after a review of over 10,000 peer-reviewed academic articles, that marijuana use is associated with:

a. respiratory problems.

b. mental health issues (such as psychosis, social anxiety, and thoughts of suicide);

c. increased risk of vehicular crashes;

d. progression to and dependence on other drugs, including studies showing connections to cocaine and heroin use;

e. learning, memory, and attention loss (possibly permanent in some cases); and low birth weight. [15]

70. The false narrative from marijuana lobby that promotes marijuana as a substitute

for opioids - in particular while an opioid epidemic is underway - is proving to be a very dangerous tactic. There is recent research showing that marijuana use is associated with an increased risk of prescription and opioid misuse disorders. [16]

71. There are a host of additional problems that come with marijuana commercialization. In Colorado, for example:

a. Residential neighborhoods, warehouse areas and even highways "reek of marijuana."

b. A homelessness growth rate that ranks among the highest rates in the country as homeless substance abusers migrate there for easy access to marijuana.

c. A doubling in the number of drivers involved in fatal crashes who tested positive for marijuana.

d. More marijuana in schools than teachers and administrators ever feared. Drug violations reported by Colorado's K-12 schools have increased 45% even as the combined number of all other violations has fallen.

e. An increase in high school drug violations of 71% since illegal commercialization.

f. School suspensions for drugs increased 45%. [17]

72. In 2020, the New York Medical Society joined forces with the State Medical Societies of New Jersey, Ohio, Pennsylvania, and Delaware to issue a joint statement stating their opposition to legalization of marijuana citing many concerning factors including data showing that despite best efforts of states to limit the purchase of legal marijuana to adults, it has also led to a troubling increase in youth use. This warning was ignored by the New York Legislature and by the Respondents. [18]

73. There has been an adequate showing of irreparable harm because the harm in this

case is that the laws are illegal, contrary to federal law, and damaging. This harm is ongoing, and cannot simply be redressed by money. Thus, the harm is irreparable. If the court were to deny the injunction, the hardship to New York residents including children, as well as to the Petitioners would be severe. Marijuana products can be very concentrated in potency and reach 99% THC, the psychoactive, intoxicating, mind-altering component of the drug. These products cause addiction, mental illness, birth defects, suicide, violence, DUIs and many adverse general health problems. (Exhibit 4). Conversely, if the court were to grant the injunction, Respondents' hardships would be slight. They would have to comply with federal law, a duty they already have.

CAUSES OF ACTION

COUNT ONE

SEVERAL ACTIONS OF THE RESPONDENTS ARE PREEMPTED BY FEDERAL LAW INCLUDING THE SUPREMACY AND COMMERCE CLAUSES OF THE UNITED STATES CONSTITUTION AND ARE THUS ILLEGAL

74. The Actions of the State are illegal under the Supremacy and Commerce Clauses and the Controlled Substances Act and are thus subject to challenges under Article 78. The state law is preempted by federal law. Conflict preemption occurs where state law actually conflicts with federal law, including where it is impossible for a private party to comply with both state and federal requirements, or where state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.

75. The United States Constitution declares that the United States Constitution and all United States' laws "shall be the supreme Law of the Land." U.S. Const. Art. VI, cl. 2. Notwithstanding New York's legalization of the medical and recreational use of marijuana, under

the federal Controlled Substances Act (CSA) the rules in question are invalid because under the Supremacy Clause of the United States Constitution, U.S. Const. art. VI, cl. 2, "state laws that interfere with, or are contrary to the laws of congress, made in pursuance of the constitution' are invalid." Wis. Pub. Intervenor v. Mortier, 501 U.S. 597, 604 (1991)).

76. Marijuana is not a "states' rights" issue under the U.S. Constitution. The Supreme court has upheld under the Commerce Clause as constitutional the application of the federal Controlled Substances Act (CSA) to the intrastate growth and possession of marijuana. The Supremacy Clause unambiguously provides that if there is any conflict between federal and state law, federal law shall prevail." Gonzales v. Raich, 545 U.S. 1 (2005). See, United States v. Oakland Cannabis Buyers' Cooperative, 532 U.S. 483, 490 (2001) (holding that there is no medical-necessity exception to the Controlled Substances Act's prohibitions on manufacturing and distributing marijuana).

77. When a party cannot satisfy its state duties without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for pre-emption purposes. Accordingly, laws cannot "permit" the sale, distribution, or consumption of illegal marijuana/cannabis products. PLIVA, Inc. v. Mensing, 564 U.S. 604, 617 (2011).

78. In US v. Hicks, 722 F.Supp.2d 829 (ED MI 2010). the court held that it is indisputable that state "medical" marijuana laws cannot supersede federal laws that criminalize the possession of marijuana. Even though a state passes a "medical" marijuana law the distribution of marijuana remains illegal under federal law. United States v. Dinh, 194 F.Supp.3d 353, 356 57 (WD PA 2016).

79. The New York Cannabis Law recognizes that federal law is a concern in implementing MRTA. The Cannabis Law states:

> Nothing in this act is intended to limit the authority of any district, government agency or office or employers to enact and enforce policies pertaining to cannabis in the workplace; to allow driving under the influence of cannabis; to allow individuals to engage in conduct that endangers others; to allow smoking cannabis in any location where smoking tobacco is prohibited; or to require any individual to engage in any conduct that violates federal law or to exempt anyone from any requirement of federal law or pose any obstacle to the federal enforcement of federal law. McKinney's Cannabis Law 2 Legislative findings and intent Effective: March 31, 2021(Emphasis added)

80. The Respondents' stated "intent" that the Cannabis Law contains "nothing" to require individuals to violate federal law or exempts them from "any requirement" of federal law, or pose any obstacle to the enforcement of federal law, is an attempt to use clever wording to avoid consequences. The evidence, however, will show that these claims are meritless and to assert them is an affront to the integrity of this court and the judicial process itself. The New York Cannabis Law is illegal and unconstitutional because it permits positive conflict with federal law and will require state employees to be in conflict with federal law

81. The Respondents' rules are preempted by the federal Controlled Substances Act. Congress enacted the CSA for the purposes of consolidating various drug laws into a comprehensive statute, providing meaningful regulation over legitimate sources of drugs to prevent diversion into illegal channels, and strengthening law enforcement tools against international and interstate drug trafficking. 21 U.S.C. 801. The Congressional findings in the CSA provide the Commerce Clause and international treaty legal justification for the CSA in the Congressional Findings section of the CSA.

> 21 U.S.C.A. § 801
> § 801. Congressional findings and declarations: controlled substances
> The Congress makes the following findings and declarations:

(1) Many of the drugs included within this subchapter have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people.
(2) The illegal importation, manufacture, distribution, and possession and improper use of controlled substances have a substantial and detrimental effect on the health and general welfare of the American people.
(3) A major portion of the traffic in controlled substances flows through interstate and foreign commerce. Incidents of the traffic which are not an integral part of the interstate or foreign flow, such as manufacture, local distribution, and possession, nonetheless have a substantial and direct effect upon interstate commerce because--
(A) after manufacture, many controlled substances are transported in interstate commerce,
(B) controlled substances distributed locally usually have been transported in interstate commerce immediately before their distribution, and
(C) controlled substances possessed commonly flow through interstate commerce immediately prior to such possession.
(4) Local distribution and possession of controlled substances contribute to swelling the interstate traffic in such substances.
(5) Controlled substances manufactured and distributed intrastate cannot be differentiated from controlled substances manufactured and distributed interstate. Thus, it is not feasible to distinguish, in terms of controls, between controlled substances manufactured and distributed interstate and controlled substances manufactured and distributed intrastate.
(6) Federal control of the intrastate incidents of the traffic in controlled substances is essential to the effective control of the interstate incidents of such traffic.
(7) The United States is a party to the Single Convention on Narcotic Drugs, 1961, and other international conventions designed to establish effective control over international and domestic traffic in controlled substances.

82. Except as otherwise authorized, the CSA makes it unlawful to knowingly or intentionally "possess with intent to manufacture, distribute, or dispense, a controlled substance." 21 U.S.C. 841(a)(1). The CSA also makes unlawful, subject to exceptions, the knowing or intentional possession of a controlled substance "unless such substance was obtained directly, or pursuant to a valid prescription or order, from a practitioner, while acting in the course of his professional practice." Id. 844(a).

83. The New York Cannabis Law is subject to the Commerce Clause as decided

recently by the federal District Court for the Northern District of New York in the case of Variscite NY One v. State of New York, 2022 WL 17257900 (ND NY November 10, 2022).

84. The CSA does not condone any conflict with federal law. 21 USC 903 on the application of state law provides that:

> No provision of this subchapter shall be construed as indicating an intent on the part of the Congress to occupy the field in which that provision operates, including criminal penalties, to the exclusion of any State law on the same subject matter which would otherwise be within the authority of the State, unless there is a positive conflict between that provision of this subchapter and that State law so that the two cannot consistently stand together". (Pub. L. 91 513, title II, 708, Oct. 27, 1970, 84 Stat. 1284)(emphasis added)

85. Under the terms of section 903, states are free to pass laws "on the same subject matter" as the Controlled Substances Act unless there is a "positive conflict" between state and federal law "so that the two cannot consistently stand together." The states have no authority to regulate commerce in marijuana or to enter into the marijuana interstate market place. By their actions to promote marijuana they are doing more than just regulating the drug and they are entering the market place. Only the federal government can regulate its sales and commerce. United States v. Oakland Cannabis Buyers' Co-op., 532 U.S. 483, 489-90 (2001) (citing 21 U.S.C. 841(a)(1), 823(f)).

86. Marijuana is classified under federal law as a Schedule I drug because: (1) the drug has a high potential for abuse; (2) the drug has no currently accepted medical use in treatment in the United States; and (3) there is a lack of accepted safety for use of the drug under medical supervision. 21 U.S.C. 811, 812(b). Gonzales v. Raich, 545 U.S. 1, 15 (2005). That original placement reflected concerns among legislators at the time about the increasing prevalence of marijuana, particularly among young people, see 116 Cong. Rec. 33,649-50

(statements of Reps. Anderson and Keith). That concern is even more real today. See, "Weed is Literally Blowing Young Mens Minds" (Exhibit 5)

87. The DEA and FDA have decided to keep marijuana as a Schedule I drug. Elansari v. United States, 2016 WL 4415012 (MD PA 2016); US v. Pickard, 100 F.Supp.3d 981, 1007 1009 (D CA 2015); Summary of the Medical Application of Marijuana: a Review of Published Clinical Studies, U.S. FDA Center for Drug Evaluation and Research, 81 Fed. Reg. 53767 (August 12, 2016).

88. Classification of marijuana as a Schedule I controlled substance is not arbitrary or capricious or a violation of due process. U.S. v. Greene, 892 F.2d 453 (CA6 1989), certiorari denied 110 S.Ct. 2179. As a Schedule I drug, the manufacture, distribution or possession of marijuana is a criminal offense under the CSA. For example:

a. It is unlawful for any person knowingly or intentionally to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance unless it is in accordance with the CSA. 21 U.S.C. 841(a)

b. It is unlawful for any person knowingly or intentionally to possess a controlled substance unless such substance was obtained directly, or pursuant to a valid prescription or order, from a practitioner. This exception does not apply to Schedule I drugs such as marijuana, which has no accepted medical use. 21 U.S.C. 844(a)

c. It is unlawful to use any communication facility such as the Internet to commit felony violations of the CSA. 21 U.S.C. 843

d. It is illegal to conspire to commit any of the crimes set forth in the CSA. 21 U.S.C. 846

e. It is unlawful to knowingly open, lease, rent, maintain, or use property for the manufacturing, storing, or distribution of controlled substances. 21 U.S.C. 856. This applies to landlords.

f. It is unlawful to distribute or manufacture controlled substances within 1,000 feet of schools, colleges, playgrounds, and public housing facilities, and within 100 feet of any youth centers, public swimming pools, and video arcade facilities. 21 U.S.C. 860

89. Federal law also states that "[w]hoever, knowing that an offense against the United States has been committed, receives, relieves, comforts or assists the offender in order to hinder or prevent his apprehension, trial or punishment, is an accessory after the fact." (18 U.S.C. 3). Under 18 U.S.C. 4, "[w]hoever, having knowledge of the actual commission of a felony cognizable by a court of the United States, conceals and does not as soon as possible make known the same to some judge or other person in civil or military authority under the United States, shall be fined under this title or imprisoned not more than three years, or both."

90. State and local government employees are not immune from prosecution. For an official to be "lawfully engaged" in the enforcement of a law relating to controlled substances, however, and therefore entitled to protection under statute creating immunity from federal drug laws, the law that the official is "enforcing" must itself be consistent with federal law and the New York marijuana rules are not. United States v. Rosenthal, 266 F.Supp.2d 1068, 1078 (ND CA 2003). 21 U.S.C. 885(d).

91. Under the state's rules on "medical" marijuana, 9 NYCRR 113 physicians may assist a registered qualifying patient or his caregiver to obtain marijuana by giving them a "certification." This is far more than just a physician discussing with a patient the use of medical

marijuana which may be protected by the First Amendment of the Constitution. This is taking an action to facilitate the use of marijuana. These actions by a physician may violate federal law by acting with specific intent to provide the patient with the means to acquire marijuana knowing that the patient intends to acquire marijuana. Conant v. Walters, 309 F.3d 629 (CA 9 2002); cert denied Walters v. Conant, 540 U.S. 946 (U.S. Oct 14, 2003). Because state marijuana is not approved as a medicine under federal law, it cannot be prescribed. Physicians have to follow federal law in writing prescriptions. 21 CFR § 1306.04; Wilcox v. Louisiana State Bd. of Medical Examiners, 446 So.2d 502 (Ct. App. La. 1984). It can be "recommended" under the state laws which supposedly avoids the federal law problem but in practice a prescription and a recommendation are the same. The New York rules puts these physicians in jeopardy.

92. Preemption may be either expressed or implied. Congress may choose to preempt state law with the express language of an enactment. In the alternative, there are two forms of implied preemption: field and conflict. Field preemption applies where the scheme of federal regulation is so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it. Gade v. National Solid Wastes Management Association, 112 S.Ct. 2374 (1992). Express and field preemption do not apply to the present matter, because the CSA explicitly leaves room for state law to operate:

> No provision of this subchapter shall be construed as indicating an intent on the part of the Congress to occupy the field in which that provision operates, including criminal penalties, to the exclusion of any State law on the same subject matter which would otherwise be within the authority of the State, unless there is a positive conflict between that provision of this subchapter and that State law so that the two cannot consistently stand together. 21 U.S.C. 903

93. Petitioners' preemption cause of action focuses on conflict preemption. Conflict

preemption occurs in two scenarios. First, conflict preemption arises "where it is impossible for a private party to comply with both state and federal requirements." PLIVA, Inc. v. Mensing, 564 U.S. 604, 618 (2011). The second context in which conflict preemption applies is when "state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." "When there is a conflict, the federal law must prevail.' Free v. Bland, 369 U.S. 663, 666 (1962)). The relative importance to the state of its own law is not material when that law conflicts with a valid federal statute. Fidelity Fed. Sav. & Loan Ass'n v. de la Cuesta, 458 U.S. 141 (1982).

94. Medical Cannabis as Provided for in 9 NYCRR 113 is preempted. Despite the clear federal laws against using marijuana as a medicine, Respondents proceeded to write into law the fiction that marijuana is a medicine. This was arbitrary and capricious. Gonzales v. Raich, 545 U.S. 1, 15, 22 (2005); Nat'l Org. for Reform of Marijuana Laws (NORML) v. Bell, 488 F.Supp. 123, 136 (D.D.C.1980); US v. Pickford, 100 F.Supp.3d 981, 1007-1009 (D CA 2015), 21 U.S.C. 812.21; 21 U.S.C. 331 and 355 (b)(1)(drug must be safe and effective in use); U.S. v. Inzer, 2015 WL 3404672 (MD FL 2015).

95. Unless a marijuana product has been approved by the FDA as a medicine under the federal Food, Drug and Cosmetic Act (FDCA), it may be neither safe or effective and puts patients at risk and is illegal under federal law. 21 U.S.C. 321 (g)(1) and (p). When a medicine's benefits outweigh its known risks, the FDA considers it "safe" enough to approve. A drug is "effective" if there is general recognition among experts, founded on substantial evidence, that the drug in fact produces results claimed for it under prescribed conditions. The FDA has only approved one CBD product as a medicine for two rare seizures disorders. It is free of THC. All

of the other claims made for botanical marijuana can be considered to be false and illegal under the FDCA and such products cannot be sold in interstate commerce. 21 U.S.C. 321(g)(1) and (p); 331(a) and (d); 352 and 355 (drug must be safe and effective in use and not be misbranded). [19] The FDA approval of a drug, however, is not the only test for determining "currently accepted medical use." A drug may also meet a five-part test:

a. The drug's chemistry must be known and reproducible;

b. there must be adequate safety studies;

c. there must be adequate and well-controlled studies proving efficacy;

d. the drug must be accepted by qualified experts; and

e. the scientific evidence must be widely available. Alliance for Cannabis Therapeutics v. DEA, 15 F.3d 1131,1135 (CA DC 1994).

96. According to the FDA and the DEA, marijuana has not met these tests primarily because the quality and design of studies cited for marijuana as medicine do not come close to satisfying FDA standards for determining safety and effectiveness. [20]

97. Recently, the Commissioner of the FDA stated that:

> Cannabis and cannabis-derived products claiming in their marketing and promotional materials that they're intended for use in the diagnosis, cure, mitigation, treatment, or prevention of diseases (such as cancer, Alzheimer's disease, psychiatric disorders and diabetes) are considered new drugs or new animal drugs and must go through the FDA drug approval process for human or animal use before they are marketed in the U.S. Selling unapproved products with unsubstantiated therapeutic claims is not only a violation of the law, but also can put patients at risk, as these products have not been proven to be safe or effective. This deceptive marketing of unproven treatments raises significant public health concerns, as it may keep some patients from accessing appropriate, recognized therapies to treat serious and even fatal diseases. [21]

98. Here are some of the facts that show the actions of the state stand as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress when it

comes to medicine and product labeling and advertising.

99. The rule permits advertising under 9 NYCRR 113.17 Medical Cannabis Marketing and Advertising. Advertising is defined as:

> 9 NYCRR 113.1 Definitions.
> (b) Advertising means disseminating communications in any manner or by any means, for the purpose of causing, directly or indirectly, the purchase or use of a medical cannabis product brand or medical cannabis product. including but not limited to websites, social media, brochures, prints ads. TV. radio, streaming, out of home, and digital advertisements.

100. 9 NYCRR 113.17 goes on the say this about "medical" marijuana providers (a/k/a) registered organizations:

> (2) A registered organization may engage in reasonable advertising practices that are not otherwise prohibited in this Part, provided the marketing and advertising does not jeopardize public health or safety, promote youth use, or be attractive to individuals under twenty-one (21) as set forth in section 113.12(k)(1) of this Part.

101. There are similar provisions in the 9 NYCRR 129 Adult Use Marketing and Advertising adopted on March 22, 2023. Such advertising is illegal under federal law because marijuana is a Schedule 1 drug. 9 NYCRR 113 and 129 are illegal and preempted. See the excerpts below from 21 U.S.C. 843 (b) of the Controlled Substances Act.

> (b) Communication facility
> It shall be unlawful for any person knowingly or intentionally to use any communication facility in committing or in causing or facilitating the commission of any act or acts constituting a felony under any provision of this subchapter or subchapter II. Each separate use of a communication facility shall be a separate offense under this subsection. For purposes of this subsection, the term "communication facility" means any and all public and private instrumentalities used or useful in the transmission of writing, signs, signals, pictures, or sounds of all kinds and includes mail, telephone, wire, radio, and all other means of communication.
> (c) Advertisement
> (1) It shall be unlawful for any person to place in any newspaper, magazine, handbill, or other publications, any written advertisement knowing that it has the purpose of seeking or offering illegally to receive, buy, or distribute a Schedule1 I controlled substance. As used in this section the term "advertisement" includes, in addition to its ordinary meaning, such advertisements as those for a catalog of Schedule1 I controlled substances

and any similar written advertisement that has the purpose of seeking or offering illegally to receive, buy, or distribute a Schedule1 I controlled substance. The term "advertisement" does not include material which merely advocates the use of a similar material, which advocates a position or practice, and does not attempt to propose or facilitate an actual transaction in a Schedule1 I controlled substance.

102. The rule 9 NYCRR 113 permits "medical cannabis" to be used as a medicine.

Cannabis Law Part 113.1 DEFINITIONS MEDICAL CANNABIS
(h) Certified medical use means the acquisition, cultivation, manufacture, delivery, harvest, possession, preparation, transfer, transportation, or use of medical cannabis for a certified patient, or the acquisition, administration, cultivation, manufacture, delivery, harvest, possession, preparation, transfer, or transportation of medical cannabis by a designated caregiver or designated caregiver facility, or paraphernalia relating to the administration of cannabis, including whole cannabis flower, to treat or alleviate a certified patient's medical condition or symptoms associated with the patient's medical condition.

103. This is a direct conflict with federal law. New York State defines marijuana as a "medicine" to treat illnesses. Using marijuana/cannabis such as Delta 8, 9 or 10 THC or CBD to treat illness unless approved by the FDA is illegal under federal law and Petitioners believe it is medical malpractice and fraudulent. See the attached article. (Exhibit 6).

104. Congress explicitly preserved the FDA's authority to regulate these products under the Federal Food, Drug, and Cosmetic Act and section 351 of the Public Health Service Act. These compounds are subject to the same requirements as FDA-regulated medicines containing any other substance regardless of the source of the substance. Cannabis products claiming in their marketing materials that they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of diseases must go through the FDA drug approval process for human or animal use before they are legally marketed. [22]

105. The New York State law rule list specific conditions for which marijuana can be

obtained in 9 NYCRR 113.1 (h). The State's legalization of "medical marijuana" has not been accompanied by the rigorous scientific approval process that have made FDA-approved medications safe and effective. "Medical marijuana" was approved for conditions where research is inadequate or missing. Petitioners will submit expert reports to that effect.

106. Respondents have been partially honest in that they admit that they do not have FDA approval. Thus, they are in violation of federal law. The state requires this warning in 9 NYCRR 113.13(j)(11)

> (11) language stating that "This product has not been analyzed by the FDA. There is limited information on the side effects of using this product and there may be associated health risks."

They admit that "There is limited information on the side effects of using this product." If that is the case, why are they allowing it as a medicine? That is dangerous, arbitrary and capricious and unreasonable.

107. Respondents should be warning the citizens of New York that although the state law authorizes use of marijuana for medical and recreational purposes, it still violates federal laws. In New Jersey their marijuana rules have issued such warnings. To not do so is to proceed under the false pretense that the sale and distribution of marijuana is "legal." It is not. The State of New Jersey in its state marijuana/cannabis rules issued this warning to marijuana/cannabis businesses and others. 2021 NJ REG TEXT 594026 (NS)

> 53 N.J.R. 1583(a) (September 20, 2021)
> Federal Standards Analysis: The Controlled Substances Act, 21 U.S.C. 801 et seq., prohibits the cultivation, distribution, and possession of marijuana, for any reason, regardless of state law. 21 U.S.C. 841 et seq. The new rules anticipate that members of the regulated community would cultivate, distribute, and possess marijuana, and may engage in certain financial activities that are ancillary to cultivation, distribution, and possession of marijuana. These ancillary financial activities may constitute prohibited conduct under other Federal criminal and civil laws, such as the money laundering

statutes, the unlicensed money transmitter statute, and the Bank Secrecy Act (BSA). 18 U.S.C. 1956 through 1957, and 1960; and 31 U.S.C. 5318.

108. The New Jersey Cannabis Regulatory, Enforcement Assistance, and Marketplace Modernization Act" (CREAMMA) N.J.S.A 24:6I-55(e) states that:

> The provisions of P.L.2021, c. 16 (C.24:6I-31 et al.) concerning the development, regulation, and enforcement of activities associated with personal use cannabis, as well as acts involving personal use cannabis or cannabis items, shall not be construed:
> e. To require a person to violate a federal law; or
> f. To exempt a person from a federal law or obstruct the enforcement of a federal law.

109. In the definitions section of Respondents' 9 NYCRR 113.1 rules they define the "conditions" that a person must have to be given marijuana/cannabis as medicine as follows:

> (k) Condition means having one of the following conditions: cancer, positive status for human immunodeficiency virus or acquired immune deficiency syndrome, amyotrophic lateral sclerosis, Parkinson's disease, multiple sclerosis, damage to the nervous tissue of the spinal cord with objective neurological indication of intractable spasticity, epilepsy, inflammatory bowel disease, neuropathies, Huntington's disease, post-traumatic stress disorder, pain that degrades health and functional capability (where the use of medical cannabis is an alternative to opioid use), substance use disorder, Alzheimer's, muscular dystrophy, dystonia, rheumatoid arthritis, autism or any other condition certified by the practitioner.

110. In other words, there is no limit on what a practitioner can do. Exhibit 4 discusses the risks of marijuana/cannabis use for many medical conditions and the dangers of marijuana use to treat those illnesses. This includes many of the conditions listed in the Respondents' rules. Patients and medical care providers and designated caregivers and designated caregiver facilities and dispensaries need to issue warnings about these risks. To not do so is cruel and negligent because sick people will otherwise think that marijuana is safe to use and they may be harmed.

111. The warnings Respondents require in section 9 NYCRR 113.17 Medical Cannabis Marketing and Advertising. (a) General Requirements, are woefully inadequate and border on the barbaric when it comes to pregnant women and their innocent children. In the case

of pregnant or nursing mothers seeking treatment for any illness the State needs to warn them not to use marijuana and the State needs to be far more specific and forceful. Respondents require only:

(4) Any marketing or advertisement of medical cannabis or medical cannabis products shall include the following statements, in a conspicuous manner on the face of the marketing material or advertisement or be read aloud clearly at the same volume and pace as the rest of the advertisement:
(i) "Keep out of reach of children and pets.";
(ii) "In case of accidental ingestion or overconsumption, contact the National Poison Control Center hotline 1-800-222-1222 or call 9-1-1.";
(iii) "Please consume responsibly."; and
(iv) any other statements or warnings as directed by the Board.

COUNT TWO

VERIFIED HYBRID ARTICLE 78 PETITION AND REQUEST FOR A DECLARATORY JUDGMENT

112. Petitioners repeat and reallege the foregoing allegations as if fully set forth herein.

113. Petitioners bring this hybrid action as an Article 78 proceeding in the nature of prohibition, pursuant to the New York State Civil Practice Law and Rules 7803 (2), and as an action for Declaratory Judgment pursuant to CPLR 3001. Petitioners are seeking to end Respondents' unconstitutional policymaking and to compel Respondents to obey federal food and drug laws that protect the citizens of New York.

114. As a result of Respondents' improper foray into the Congress's legislative terrain, Respondents have created a marijuana trafficking scheme that could not be more at odds with what Congress intended in passing our national food and drug laws regarding marijuana. An Article 78 review and relief is available any time an agency acts unlawfully, beyond its jurisdiction, or in a capricious manner.

115. The Respondents have engaged in the usurpation of Congressional powers since it is the province of the people's elected representatives in Congress rather than appointed administrators in New York to decide national food and drug laws as they relate to marijuana trafficking and medicine. The actions of Respondents violate New York's separation of powers doctrine. In addition, neither the state legislature nor the Respondents have the technical competence of the Drug Enforcement Administration (DEA) or the Food and Drug Administration (FDA) to make these decisions. The DEA and the FDA have decided that marijuana should be a schedule I drug. Their decision has been upheld by the federal courts.

116. The Respondents' actions meet the criteria to be challenged in an Article 78 proceeding under CPLR 7803 as follows:

a. Respondents failed to obey a duty enjoined upon them by federal law. The Respondents with full knowledge of their violation of federal law took willful, unreasonable actions without consideration of or in disregard of the law. They had no rational basis to violate federal law and acted in a capricious manner. They chose to ignore federal statutory obligations.

b. By approving marijuana as a medicine, and in approving use of marijuana as a food in violation of federal food and drug laws, they acted in excess of jurisdiction.

c. Respondents made their determinations in violation of lawful procedure (medicine not approved by the FDA), and it was affected by an error of law and was capricious and an abuse of discretion. Abuse of discretion, which is specifically identified in CPLR 7803(3) as a ground for Article 78 review, can apply either to the content of the agency's determination or the procedure the agency followed in reaching the determinations.

d. In addition, the agencies involved lacked regulatory competence to make these decisions.

117. The actions of the Respondents pose a threat of harm to one or more of the members and clients of the two associations and the associations have standing to bring an Article 78 proceeding if one or more of its members has standing. A "private right of action" is not required. Association members live in close proximity to marijuana trafficking stores that affect the area's safety, cleanliness, and character; the interests the associations seek to protect are germane to their purposes. The property or personal rights and environmental rights of the Petitioners are affected. They seek to challenge the scheme under which marijuana trafficking in their neighborhoods receives government fiscal support and is generally conducted.

118. Under Chapter 7-A of the New York Consolidated Laws, the actions of Respondents are unconstitutional and should be struck entirely or, alternatively, to sever all procedurally and substantively unconstitutional parts

119. The state agencies did not exercise any special expertise or technical competence in making these decisions, or if they did, it was faulty. Following the appointment of CCB's Chairperson, Tremaine Wright, then-Senator Diane Savino commented as follows "You [Tremaine Wright] have experience in a lot of things but I'm concerned you don't have direct experience with cannabis or the cannabis industry itself." For all of the reasons set forth above, it is clear that no real expertise was applied, or it was applied in a faulty manner. Respondents have ventured into the role of the Congress and FDA and DEA to attempt a work-around to the federal law. [23]

COUNT THREE

RESPONDENTS DECEPTIVELY CITE FEDERAL LAW IN THEIR MEDICAL CANNABIS AND THEIR ADULT USE PACKAGING AND LABELING RULES. THEY SHOULD BE ENJOINED FROM THIS DECEPTION AND FOR BEING ARBITRARY AND CAPRICIOUS, AND IN VIOLATION OF LAWFUL PROCEDURE, AND/OR AFFECTED BY ERRORS OF LAW

120. Petitioners repeat and reallege the foregoing allegations as if fully set forth herein.

121. On February 3, 2023, in their comments on the proposed rules Medical Cannabis 113, CIVEL warned the Respondents of the following violations of federal law in the proposed rules. (Exhibit 1)

> **Violations of Federal Law**
> Based on an analysis of federal statutes and case law, it is clear that under federal law anyone involved in the possession, production, growing or the sale of marijuana is subject to federal prosecution under the federal Controlled Substances Act (CSA) because the state marijuana laws are preempted by the CSA. The proposed regulations also violate state and federal food and drug laws and federal consumer protection and fraud laws such as NY Title 22 General Business Law section 349 and federal products for human consumption laws and the Lanham Act 15 U.S.C. 22 There is also the Racketeer Influenced and Corrupt Organizations Act (RICO). 18 U.S.C. 1962. The federal laws are authorized by the Commerce Clause of the US Constitution. Congress enacted the CSA for the purposes of consolidating various drug laws into a comprehensive statute, providing meaningful regulation over legitimate sources of drugs to prevent diversion into illegal channels, and strengthening law enforcement tools against international and interstate drug trafficking. 21 U.S.C. 801 et seq.

122. The Respondents were also informed that:

> Anyone who participates in the growing, possession, manufacturing, distribution, or sales of marijuana under state law or aids or facilitates or finances such actions is at risk of federal prosecution or other liability. We urge you to stand up to the marijuana industry that has come to dominate your state government. The government of New York should not permit the implementation of any state law that is contrary to federal law.
>
> Please be advised that we considering to litigate these and other matters having to do with marijuana and your illegal actions.

123. Petitioners aver that the Respondents received fair warning but despite being warned, the Respondents then adopted their Medical Cannabis 9 NYCRR 113 rule on February 22, 2023 and their Adult-Use Packaging and Labeling 9 NYCRR 128 rule on March 22, 2023. In their Medical Cannabis 9 NYCRR 113 rule Respondents cite the following federal laws in some sections of 9 NYCRR 113.

a. In 113.1(j) they cite federal law 16 CFR §1700.15 and §1700.20 (Poison prevention packaging standards)

b. In 113.6(b)(5) they cite federal law 21 CFR Parts 111 or 21 CFR Part 117 (Deals with dietary supplements)

c. In 113.12(j)(5) they cite federal law 16 CFR Part 260 (Deceptive marketing)

d. In 113.12(a)(2)(iii) they cite federal law 21 USC § 321 (Definitions - food and drug laws)

e. In 113.12(l)(1)(ii) they cite federal law 21 USC § 343 (Misbranded food)

124. In Respondents' Adult-Use Packaging and Labeling rules they cite as follows:

a. In 128.4(c) they cite federal law 16 CFR 260 (Deceptive marketing)

b. In 128.5(b)(1) they cite federal law 21 U.S.C. 343 (Nation uniform nutrition labeling

c. In 128.5(b)(1)(I) they cite federal law 21 CFR 101.9(c) (Nutrition labeling of food)

d. In 128.5(b)(1)(ii) they cite federal law 21 CFR 101.36 (Nutrition labeling of dietary supplements)

e. In 128.6(a)(3) Respondents cite federal law 7 CFR 205.600 – 205.619 (Evaluation criteria for allowed and prohibited substances and ingredients in food)

f. In 128.6(a)(5) they cite federal law 21 CFR 101.91 (Gluten -free labeling of food)

125. Respondents intend to have marijuana/cannabis products used as food and as medicine. Respondents cite 21 U.S.C.A. § 321 that defines food and medicinal drugs:

> (f) The term "food" means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.
>
> (g)(1) The term "drug" means (A) articles recognized in the official United States Pharmacopœia,1 official Homœopathic Pharmacopœia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C). A food or dietary supplement for which a claim, subject to sections 343(r)(1)(B) and 343(r)(3) of this title or sections 343(r)(1)(B) and 343(r)(5)(D) of this title, is made in accordance with the requirements of section 343(r) of this title is not a drug solely because the label or the labeling contains such a claim. A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 343(r)(6) of this title is not a drug under clause (C) solely because the label or the labeling contains such a statement.

These sections of 9 NYCRR 113 and 128 deal with medicine and food and dietary supplements. These rules are in violation of federal law because they deal with marijuana, a controlled substance. It is clear that marijuana or cannabis or THC or CBD in medicines and foods are items regulated by the federal Food and Drug Administration. The Respondents were deceptively trying to make what they are doing to appear as "legitimate."

126. You can put lipstick on a pig to make it look better, but it is still a pig. The lipstick Respondents use are the cites to various federal labeling laws for legal substances. The Respondents are acting *ultra vires* beyond the scope of the authority or power that is granted to them.

127. Here is what the FDA has to say about marijuana, CBD and THC in food and medicines in a public announcement. [24]

> Parts of the Cannabis sativa plant have been controlled under the Controlled Substances Act (CSA) since 1970 under the drug class "Marihuana" (commonly referred to as

"marijuana") [21 U.S.C. 802(16)]. "Marihuana" is listed in Schedule I of the CSA due to its high potential for abuse, which is attributable in large part to the psychoactive effects of THC, and the absence of a currently accepted medical use of the plant in the United States.

9. Can THC or CBD products be sold as dietary supplements?

A. No. Based on available evidence, FDA has concluded that THC and CBD products are excluded from the dietary supplement definition under section 201(ff)(3)(B) of the FD&C Act [21 U.S.C. § 321(ff)(3)(B)]. Under that provision, if a substance (such as THC or CBD) is an active ingredient in a drug product that has been approved under section 505 of the FD&C Act [21 U.S.C. § 355], or has been authorized for investigation as a new drug for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, then products containing that substance are excluded from the definition of a dietary supplement. FDA considers a substance to be "authorized for investigation as a new drug" if it is the subject of an Investigational New Drug application (IND) that has gone into effect. Under FDA's regulations (21 CFR 312.2), unless a clinical investigation meets the limited criteria in that regulation, an IND is required for all clinical investigations of products that are subject to section 505 of the FD&C Act.

There is an exception to section 201(ff)(3)(B) if the substance was "marketed as" a dietary supplement or as a conventional food before the drug was approved or before the new drug investigations were authorized, as applicable. However, based on available evidence, FDA has concluded that this is not the case for THC or CBD.

FDA is not aware of any evidence that would call into question its current conclusions that THC and CBD products are excluded from the dietary supplement definition under section 201(ff)(3)(B) of the FD&C Act. Interested parties may present the agency with any evidence that they think has bearing on this issue. Our continuing review of information that has been submitted thus far has not caused us to change our conclusions.

When a substance is excluded from the dietary supplement definition under section 201(ff)(3)(B) of the FD&C Act, the exclusion applies unless FDA, in the agency's discretion, has issued a regulation, after notice and comment, finding that the article would be lawful under the FD&C Act. To date, no such regulation has been issued for any substance.

Ingredients that are derived from parts of the cannabis plant that do not contain THC or CBD might fall outside the scope of this exclusion, and therefore might be able to be marketed as dietary supplements. However, all products marketed as dietary supplements must comply with all applicable laws and regulations governing dietary supplement products. For example, manufacturers and distributors who wish to market dietary supplements that contain "new dietary ingredients" (i.e., dietary ingredients that were not marketed in the United States in a dietary supplement before October 15, 1994) generally

must notify FDA about these ingredients (see section 413(d) of the FD&C Act [21 U.S.C. § 350b(d)]). Generally, the notification must include information demonstrating that a dietary supplement containing the new dietary ingredient will reasonably be expected to be safe under the conditions of use recommended or suggested in the labeling. A dietary supplement is adulterated if it contains a new dietary ingredient for which there is inadequate information to provide reasonable assurance that the ingredient does not present a significant or unreasonable risk of illness or injury (see section 402(f)(1)(B) of the FD&C Act [21 U.S.C. 342(f)(1)(B)]).

Numerous other legal requirements apply to dietary supplement products, including requirements relating to Current Good Manufacturing Practices (CGMPs) and labeling. Information about these requirements, and about FDA requirements across all product areas, can be found on FDA's website.

10. Is it legal, in interstate commerce, to sell a food (including any animal food or feed) to which THC or CBD has been added?

A. No. Under section 301(ll) of the FD&C Act [21 U.S.C. § 331(ll)], it is prohibited to introduce or deliver for introduction into interstate commerce any food (including any animal food or feed) to which has been added a substance which is an active ingredient in a drug product that has been approved under section 505 of the FD&C Act [21 U.S.C. § 355], or a drug for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public. There are exceptions, including when the drug was marketed in food before the drug was approved or before the substantial clinical investigations involving the drug had been instituted or, in the case of animal feed, that the drug is a new animal drug approved for use in feed and used according to the approved labeling. However, based on available evidence, FDA has concluded that none of these is the case for THC or CBD. FDA has therefore concluded that it is a prohibited act to introduce or deliver for introduction into interstate commerce any food (including any animal food or feed) to which THC or CBD has been added. FDA is not aware of any evidence that would call into question these conclusions. Interested parties may present the agency with any evidence that they think has bearing on this issue. Our continuing review of information that has been submitted thus far has not caused us to change our conclusions.

When this statutory prohibition applies to a substance, it prohibits the introduction into interstate commerce of any food to which the substance has been added unless FDA, in the agency's discretion, has issued a regulation approving the use of the substance in the food (section 301(ll)(2) of the FD&C Act [21 U.S.C. § 331(ll)(2)]). To date, no such regulation has been issued for any substance.

Ingredients that are derived from parts of the cannabis plant that do not contain THC or CBD might fall outside the scope of 301(ll), and therefore might be able to be added to food. For example, as discussed in Question #12, certain hemp seed ingredients can be legally marketed in human food. However, all food ingredients must comply with all

> applicable laws and regulations. For example, by statute, any substance intentionally added to food is a food additive, and therefore subject to premarket review and approval by FDA, unless the substance is generally recognized as safe (GRAS) by qualified experts under the conditions of its intended use, or the use of the substance is otherwise excepted from the definition of a food additive (sections 201(s) and 409 of the FD&C Act [21 U.S.C. §§ 321(s) and 348]). Aside from the three hemp seed ingredients mentioned in Question #12, no other cannabis or cannabis-derived ingredients have been the subject of a food additive petition, an evaluated GRAS notification, or have otherwise been approved for use in food by FDA. Food companies that wish to use cannabis or cannabis-derived ingredients in their foods are subject to the relevant laws and regulations that govern all food products, including those that relate to the food additive and GRAS processes.

128. There are no medical randomized controlled trials (RCT) on the use of marijuana/cannabis for many of the conditions in the medical cannabis rule. This makes them arbitrary and capricious and *ultra vires*. The Defendant's rule on "medical marijuana" has not been accompanied by the rigorous scientific approval process with regulations for dosing, production, packaging and monitoring that have made FDA-approved medications safe and effective. "Medical" marijuana" is approved for conditions where research is inadequate. False advertising may mislead vulnerable patients and the public. "Medical" use may inadvertently result in addiction, increased risk of psychosis, mental or psychosocial impairment, lung damage when smoked, and complications for unborn children when used during pregnancy. The presence of "medical marijuana" dispensaries may increase access to recreational marijuana for minors. "Medical marijuana" legalization is associated with increased illicit marijuana use, is linked to increased emergency room visits for marijuana-intoxicated children. Petitioners will provide expert testimony on these points.

129. A reasonable and prudent physician should only recommend FDA-approved pharmaceutical-grade medications when the indications are clear, dosing is well-established, risk-benefit ratios have been investigated and can be applied to individual patients, delivery

systems are safe, and careful monitoring is agreed upon. There should only be legalization via FDA approval through formal clinical and scientific studies of any marijuana-based therapeutic that has demonstrated medical efficacy and safety by randomized controlled trials. In 9 NYCRR 113.13(j)(11) Respondents admit the dangers. "This product has not been analyzed by the FDA. There is limited information on the side effects of using this product and there may be associated health risks." That statement alone should be enough to enjoin 9 NYCRR 113.

130. Any marijuana or CBD product intended "for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and/or because they are intended to affect the structure or any function of the body" that has not been approved for marketing by the federal Food and Drug Administration is neither safe nor effective and puts patients at risk. Section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 321(g)(1). If not approved by the FDA, a drug has to be currently accepted for medical use in treatment in the United States and has to meet five criteria:

1. The drug's chemistry must be known and reproducible.
2. There must be adequate safety studies.
3. There must be adequate and well-controlled studies proving efficacy.
4. The drug must be accepted by qualified experts.
5. The scientific evidence must be widely available.

131. Marijuana has not met this test in federal court. [25] If marijuana has not been approved by the FDA, or met the above test, it may be fraudulent to claim that it has medicinal properties as claimed in the Medical Cannabis rule. Examples of fraud by the Respondents and their business partners in the marijuana industry include:

a. Permitting the marketing of the fraud of "medical" marijuana.

b. Marketing marijuana aggressively to people many of whom became addicted.

c. False advertising by means of false and misleading package inserts, promotion, and marketing that do not contain proper warnings.

d. False statements concerning the safety of marijuana.

e. Misbranding marijuana as less addictive and less subject to abuse and diversion and less likely to cause tolerance and withdrawal than other pain medications.

f. Misrepresentation as to side effects and harms.

g. Misrepresentations as to the respective existence, occurrence and frequency of occurrences, severity and extent of the overall risks of marijuana use.

h. Misrepresentations as to the respective efficacy of marijuana as a medicine.

1. Misrepresentations as to the respective number of adverse events and deaths reported with the use of marijuana as a medicine.

j. Misrepresentations regarding the respective nature, seriousness, and severity of adverse events reported with the use of marijuana as a medicine.

132. The are false claims for CBD. Cannabidiol (CBD) is a derivative of cannabis and one of the main active ingredients in the marijuana plant. The chemical in marijuana that causes the high (and many of its other effects) is delta-9 tetrahydrocannabinol, or THC. But there are over 100 other cannabinoid chemicals in the plant; CBD is one of those. Different cannabinoids can have very different biological effects.

133. The United States Food & Drug Administration sent numerous Warning Letters

discussing numerous violations of CBD products, including but not limited to; Dietary Supplement Labeling, Unapproved New Drugs, Misbranded Drugs, Adulterated Human Foods, Unapproved New Animal Drugs, and Adulterated Animal Foods. All of these violations of the Food, Drug and Cosmetic Act make CBD products illegal to use as a medicine or a food unless approved by the FDA. Various false medical claims for CBD have been made on the Internet (wire fraud). Below are examples of false claims that have been taken from FDA warning letters to companies that sell CBD. Such false claims include using CBD to cure or treat:

Cancer
Late-stage pancreatic cancer.
Traumatic Brain Injury (TBI)
Depression
Child cancer
Breast, glioma, Leukemia, thyroid, colon and lung cancer
Metastatic Breast Cancer
Alzheimer's disease
Diabetes
Leukemia
Lung Cancer
Parkinson's disease
Stroke
Pediatric cancer remission
Autism
Brain protection
Concussions
Chronic traumatic encephalopathy. CTE is a degenerative brain disease caused by repetitive brain trauma. [26]
Kills cancer cells and provides a protective coating around our brain cells
Diabetes
Blood pressure and heart rate
Anti-tumor [27]
Combats tumor and cancer cells
Limits neurological damage following stroke and trauma, or in the treatment of neurodegenerative diseases, such as Alzheimer's disease and Parkinson's disease.
Chemotherapy-Induced Hearing Loss
Rheumatoid arthritis
Colitis
Liver inflammation
Heart disease

Diabetes.
Schizophrenia
Alcoholism
Strokes
Cardiovascular disease
Cancer
Lupus
Lyme Disease
Stroke Victims
Arthritis
Traumatic brain injury [28]
Anti-proliferative properties that inhibit cell division and growth in certain types of cancer, not allowing the tumor to grow.
Preventing both cancer spread and growth
Asthma
Alzheimer's Disease
Arthritis
Autism
Bipolar Disorder
Various Types of Cancer
MRSA
Breast Cancer
Therapeutic Effects for the Human Body
Autism
Alzheimers [29]

134. The marijuana plant has over 400 chemicals that include tetrahydrocannabinol (THC), the psychoactive chemical and cannabidiol (CBD). These products are metabolized in the liver and may alter the metabolism of many medications resulting in toxicity or under dosing of the medications. There are 379 drug interactions with THC, 25 major and 354 minor. There are 539 drug interactions with cannabidiol (CBD), 9 major and 482 moderates. Drug interactions with marijuana products can be life threatening. Marijuana and CBD and all Cannabinoids, may interact with the following medicines:

Sedatives - such as Barbiturates, lorazepam (Klonopin), lorazepam (Ativan), phenobarbital (Donnatal), zolpidem (Ambien) and others. The sedative effect can be increased.

Theophylline - decreases the effects of theophylline which is bronchodilator - it opens up the airways in the user's lungs to make breathing easier.

Disulfiram (Antabuse) - using it and marijuana can cause agitation, trouble sleeping, and irritability.

Fluoxetine (Prozac) - using it and marijuana can cause irritation, nervousness, jitteriness, and excitation (hypomania).

Warfarin (Coumadin) - using it and marijuana can increase the chance of bruising and bleeding.

Marijuana and CBD may also interact with

Zonisamide

Eslicarbazepine acetate (Aptiom—Sunovion)

Cyclosporine

Calcium channel blockers

Benzodiazepines

Haloperidol (Haldol—Johnson & Johnson)

Atorvastatin (Lipitor—Pfizer)

Simvastatin

Antiepileptic drugs (caution with children)

Clobazam

Corticosteroids

Some hospital-administered antibiotics

Medicines that make patients lethargic (marijuana can accentuate that)

Marijuana increases the level or effect of a lot of different medications.

CBD may potentially interact in a negative way with anti-epilepsy drugs such as:

Carbamazepine (Tegretol)

Phenytoin (Dilantin)

Phenobarbital (Luminal, Solfoton, Tedral)

Primidone (anti-seizure) [30]

135. According to 21 C.F.R. 201.57(a), the following information must appear in all medicine labeling:

a. Highlights limitation statement.
b. Drug names, dosage form, route of administration, and controlled substance symbol.
c. Initial U.S. approval.
d. Boxed warning.
e. Recent major changes.
f. Indications and usage
g. Dosage and administration
h. Dosage forms and strengths.
i. Contraindications.
j. Warnings and precautions.
k. Adverse reactions.
l. Drug interactions.
m. Use in specific populations.
n. Patient counseling information statement.
o. Revision date.
p. References.
r. How supplied/storage and handling.
s. Patient Counseling information

Respondents' labeling does not even come close to this, 9 NYCRR 113 (page 66)

136. 21 C.F.R. 201.57(a) provides this about any drug such as marijuana that is controlled by the Drug Enforcement Administration. The Respondents do not do this.

(10) 9 Drug abuse and dependence. This section must contain the following information, as appropriate:
(i) 9.1 Controlled substance. If the drug is controlled by the Drug Enforcement Administration, the schedule in which it is controlled must be stated.

(ii) 9.2 Abuse. This subsection must state the types of abuse that can occur with the drug and the adverse reactions pertinent to them, and must identify particularly susceptible patient populations. This subsection must be based primarily on human data and human experience, but pertinent animal data may also be used.
(iii) 9.3 Dependence. This subsection must describe characteristic effects resulting from both psychological and physical dependence that occur with the drug and must identify the quantity of the drug over a period of time that may lead to tolerance or dependence, or both. Details must be provided on the adverse effects of chronic abuse and the effects of abrupt withdrawal. Procedures necessary to diagnose the dependent state and the principles of treating the effects of abrupt withdrawal must be described.

137. Although there is a brief warning in the state rules to not use marijuana during pregnancy they still permit health care providers to give it to pregnant women or those women who are nursing.

(f) "This product is for medicinal use only. This product should not be consumed during pregnancy or while nursing except on the advice of the certifying practitioner, and in the case of a nursing parent, including the infant's pediatrician." Part 113 Medical Cannabis page 68.

138. The Respondents do not provide the below FDA required information for pregnant women or those women who are nursing.

(C) Clinical considerations. Under the subheading "Clinical Considerations," the labeling must provide relevant information, to the extent it is available, under the headings "Disease-associated maternal and/or embryo/fetal risk," "Dose adjustments during pregnancy and the postpartum period," "Maternal adverse reactions," "Fetal/Neonatal adverse reactions," and "Labor or delivery":
(1) Disease-associated maternal and/or embryo/fetal risk. If there is a serious known or potential risk to the pregnant woman and/or the embryo/fetus associated with the disease or condition for which the drug is indicated to be used, the labeling must describe the risk.
(2) Dose adjustments during pregnancy and the postpartum period. If there are pharmacokinetic data that support dose adjustment(s) during pregnancy and the postpartum period, a summary of this information must be provided.
(3) Maternal adverse reactions. If use of the drug is associated with a maternal adverse reaction that is unique to pregnancy or if a known adverse reaction occurs with increased frequency or severity in pregnant women, the labeling must describe the adverse reaction and available intervention(s) for monitoring or mitigating the reaction. The labeling must describe, if known, the effect of dose, timing, and duration of exposure on the risk to the pregnant woman of experiencing the adverse reaction.

(4) Fetal/Neonatal adverse reactions. If it is known or anticipated that treatment of the pregnant woman increases or may increase the risk of an adverse reaction in the fetus or neonate, the labeling must describe the adverse reaction, the potential severity and reversibility of the adverse reaction, and available intervention(s) for monitoring or mitigating the reaction. The labeling must describe, if known, the effect of dose, timing, and duration of exposure on the risk. 21 C.F.R. 201.57(a)

139. To "dress up" their rules Respondents cite federal laws but leave out much crucial information. This is in conflict with federal law and an obstacle to achieving the goals of the federal law. It is arbitrary and capricious, violations of lawful procedure, and/or affected by errors of law. It will harm children.

140. The FDA has stated that CBD may not be labeled as a dietary ingredient or legally be contained within a dietary supplement. [31] Respondents' marijuana cannot be dietary supplements because they do not meet the definition of a dietary supplement under section 201(ff) of the FD&C Act, 21 U.S.C. 321(ff). The FDA has concluded, based on available evidence, that CBD products are excluded from the dietary supplement definition under sections 201(ff)(3)(B)(i) and (ii) of the FD&C Act, 21 U.S.C. 321(ff)(3)(B)(i) and (ii).

141. The Respondents' 9 NYCRR 128 - Adult-Use Packaging and Labeling rule is in violation of federal law because it deals with marijuana, a controlled substance. These products cannot be used as a food, yet, Respondents state in 9 NYCRR 128.5(b)(1) Cannabis Product Labeling Minimum Standards that:

> The cannabis product list shall include and separately list, in bold, any major allergens set forth in the Food Allergen Labeling and Consumer Protection Act of 2004, Title 21, as it relates to Food and Drugs, of the U.S. Code section 343, for misbranded food.

> (i) Edibles shall include a nutritional label pursuant to Title 21, as it relates Food and Drugs, of the Codes of Federal Regulations section 101.9(c) for nutrition labeling of food, as amended from time to time; and
> (ii) Cannabis products marketed as dietary supplements shall include a supplement fact panel pursuant to Title 21, as it relates to Food and Drugs, of the Codes of Federal Regulations section 101.36 for nutrition labeling of dietary supplements, as amended from time to time;

142. This seems to be an attempt to make it appear that these products are produced in accordance with federal law. This is fraudulent.

143. The court should note that there is no warning below in 9 NYCRR 113 about "medical" marijuana being given to pregnant or nursing women. This is very dangerous and arbitrary. There is no question that marijuana use while nursing or pregnant is dangerous.

> (4) Any marketing or advertisement of medical cannabis or medical cannabis products shall include the following statements, in a conspicuous manner on the face of the marketing material or advertisement or be read aloud clearly at the same volume and pace as the rest of the advertisement:
> (i) "Keep out of reach of children and pets.";
> (ii) "In case of accidental ingestion or overconsumption, contact the National Poison Control Center hotline 1-800-222-1222 or call 9-1-1.";
> (iii) "Please consume responsibly."; and
> (iv) any other statements or warnings as directed by the Board.

146. Given what the American College of Obstetricians and Gynecologists (ACOG) state about pregnant or nursing women using marijuana, the Respondents' packaging warnings are very unsafe, and anemic. ACOG states that:

> If you use marijuana during pregnancy, you may be putting your health and your fetus's health at risk.
> Possible Effects on Your Fetus
> Disruption of brain development before birth
> Smaller size at birth
> Higher risk of stillbirth
> Behavioral problems in childhood and trouble paying attention in school
> Higher chance of being born too early, especially when you use both marijuana and cigarettes during pregnancy
> Harm from secondhand marijuana smoke [32]

147. Here are examples of proper warnings based on what we know about marijuana:

WARNING: MARIJUANA/CANNABIS USE MAY CAUSE PHYSICAL AND MENTAL HEALTH PROBLEMS FOR USERS.

WARNING: THIS PACKAGE CONTAINS MARIJUANA/CANNABIS, A SCHEDULE I CONTROLLED SUBSTANCE. KEEP OUT OF REACH OF CHILDREN AND ANIMALS.

WARNING: THE SMOKE FROM MARIJUANA/CANNABIS IS HARMFUL AND MAY CAUSE CANCER.

WARNING: DO NOT USE IF PREGNANT OR BREASTFEEDING. SUBSTANCES IN MARIJUANA/CANNABIS ARE TRANSFERRED FROM THE MOTHER TO CHILD AND CAN HARM YOUR BABY.

WARNING: DO NOT DRIVE OR OPERATE HEAVY EQUIPMENT AFTER USING MARIJUANA/CANNABIS. MARIJUANA/CANNABIS CAN CAUSE DROWSINESS AND IMPAIR YOUR ABILITY TO CONCENTRATE AND MAKE QUICK DECISIONS.

WARNING: FREQUENT AND PROLONGED USE OF MARIJUANA/CANNABIS CAN CONTRIBUTE TO MENTAL HEALTH PROBLEMS OVER TIME. DAILY OR NEAR-DAILY USE INCREASES THE RISK OF DEPENDENCE AND MAY BRING ON OR WORSEN DISORDERS RELATED TO ANXIETY AND DEPRESSION.

WARNING: ADOLESCENTS AND YOUNG ADULTS ARE AT GREATER RISK OF HARMS FROM MARIJUANA/CANNABIS. DAILY OR NEAR-DAILY USE OVER A PROLONGED PERIOD OF TIME CAN HARM BRAIN DEVELOPMENT AND FUNCTION.

WARNING: THE HIGHER THE THC CONTENT OF A PRODUCT, THE MORE LIKELY YOU ARE TO EXPERIENCE ADVERSE EFFECTS AND GREATER LEVELS OF IMPAIRMENT. THC CAN CAUSE ANXIETY AND IMPAIR MEMORY AND CONCENTRATION.

WARNING: IT CAN TAKE UP TO 4 HOURS TO FEEL THE FULL EFFECTS FROM EATING OR DRINKING MARIJUANA/CANNABIS. CONSUMING MORE WITHIN THIS TIME PERIOD CAN RESULT IN ADVERSE EFFECTS THAT MAY REQUIRE MEDICAL ATTENTION.

WARNING: THE EFFECTS FROM EATING OR DRINKING MARIJUANA/CANNABIS CAN BE LONG-LASTING. THE EFFECTS CAN LAST BETWEEN 6 AND 12 HOURS FOLLOWING USE.

WARNING: MARIJUANA/CANNABIS USE MAY CAUSE PSYCHOTIC SYMPTOMS AND/OR PSYCHOTIC DISORDER (DELUSIONS, HALLUCINATIONS, OR DIFFICULTY DISTINGUISHING REALITY OR OTHER MENTAL HEALTH SYMPTOMS/PROBLEMS SUCH AS DEPRESSION AND SUICIDAL IDEATION

WARNING: MARIJUANA/CANNABIS USE MAY CAUSE CANNABIS HYPEREMESIS SYNDROME (CHS) (UNCONTROLLED AND REPETITIVE VOMITING)

WARNING: MARIJUANA/CANNABIS USE MAY CAUSE CANNABIS USE DISORDER OR DEPENDENCE, INCLUDING PHYSICAL AND PSYCHOLOGICAL DEPENDENCE.

WARNING: MARIJUANA USE IS NOT APPROVED BY THE FDA AS BEING SAFE OR EFFECTIVE AS MEDICINE.

WARNING: MARIJUANA/CANNABIS USE MAY CAUSE DAMAGE TO REPRODUCTIVE HEALTH IN MEN AND WOMEN

148. The marijuana/cannabis health warning message should also apply to marijuana/cannabis products that are marijuana/cannabis topicals.

WARNING: DO NOT SWALLOW OR APPLY INTERNALLY OR TO BROKEN, IRRITATED OR ITCHING SKIN. THERE MAY BE HEALTH EFFECTS AND RISKS ASSOCIATED WITH MARIJUANA/CANNABIS TOPICALS THAT ARE NOT FULLY KNOWN OR UNDERSTOOD.

149. By asserting the fantasy that Respondents are somehow in compliance with federal food and drug laws, the Respondents are being deceptive, fraudulent, reckless and cynical.

150. The Respondents, and the marijuana traffickers they are financing, will be running afoul of federal food and drug and consumer protections and product safety laws including:

a. 5 U.S.C.A. § 2072 that provides for suits for damages for violation of a consumer product safety rules.

b. 15 U.S.C.A. 52. False advertising. See also16 CFR 2.2; 16 CFR § 2.3.;16 CFR § 1.6; 16 CFR 1.9; 16 CFR § 1.15 .

c. 15 U.S.C.A. 2068 Prohibited acts. It is unlawful for any person to sell, offer for sale, manufacture for sale, distribute in commerce, any consumer product, or other product or substance that is not in conformity with applicable consumer product safety rule.

d. Magnuson-Moss Breach of Express Warranty 15 U.S.C. § 2301 *et seq*. Under that law a "consumer" as defined in 15 U.S.C. § 2301(3) is one who purchased the products subject to Defendant's express warranty, and who is entitled by the terms of the warranty to enforce against the Defendant the obligations of same.

151. The US Department of Justice filed U.S. v. Philip Morris, a civil Racketeer Influenced and Corrupt Organizations Act (RICO) lawsuit, against the major tobacco companies for making fraudulent claims about their products. The lawsuit was largely based on wire and mail fraud. The mail fraud statute makes it illegal to use the mail to defraud or to obtain money or property by means of false or fraudulent representations. 18 U.S.C. § 1341. The wire fraud law is similar and applies to the use of television, radio, and wire communications and other modes of communication, such as telephones, facsimile machines, and the Internet. 18 U.S.C. 1343

152. The government won the lawsuit. In the opening statement of the court's opinion the court laid out a devastating indictment of what the tobacco companies have done fraudulently to sell their products that have addicted and killed millions of Americans. If you take the

references to tobacco out of this statement and put in references to marijuana, there is a match. [33] What the tobacco companies have done the marijuana companies are doing now. It is only a matter of time before there are RICO lawsuits against marijuana stores and growing operations in New York.

152. Petitioners respectfully request that the Rules regarding medical cannabis and labeling and advertising be enjoined and brought into compliance with federal law.

PRAYER FOR RELIEF

Petitioners pray for relief as follows:

a. For a judgment annulling and vacating the below cannabis rules adopted on or after February 22, 2023 as they are unconstitutional, null and void, and are capricious and arbitrary and thus enjoined.

i. Medical Cannabis, 9 NYCRR 113 adopted 2/22/23

ii. Adult-Use Packaging and Labeling, 9 NYCRR 128 adopted 3/22/2023

iii. Adult-Use Marketing and Advertising, 9 NYCRR 129 adopted 3/22/2023

b. Declaratory relief stating those rules are preempted and in conflict with federal law.

c. Cost of the action.

d. Reasonable attorney's fees, to the extent that the law allows.

e. or such other and further relief as the Court may deem just and proper.

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Dated June 20, 2023

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Footnotes

1. Marijuana is one variety of plants in the Cannabis family and Cannabis often is used as a synonym for marijuana. Thus, for the purposes of this Complaint, marihuana, marijuana, and cannabis all refer to the same plant substance officially known as cannabis Sativa L. The New York Cannabis legalization law is entitled "Marihuana Regulation and Taxation Act." Federal law refers to it as "marijuana." Marijuana is a derivative of the cannabis plant as are other cannabinoids such as cannabidiol (CBD).

2. Petitioners urge that this rule be implemented properly. Colorado regulators have identified "many examples" of licensed marijuana businesses cheating lab testing. https://mjbizdaily.com/many-examples-of-marijuana-testing-cheaters-in-colorado-regulators-say

3. Article VI, Sect. 2 of U.S. Constitution: "This Constitution, and the laws of the United States which shall be made in pursuance thereof; and all treaties made, or which shall be made, under the authority of the United States, shall be the supreme law of the land; and the judges in every state shall be bound thereby, anything in the Constitution or laws of any State to the contrary notwithstanding."

4. UNIS/NAR/1190, 11 December 2013, Uruguay is breaking the International Conventions on Drug Control with the Cannabis Legislation approved by its Congress http://incb.org/documents/Publications/PressRelease/PR2013/press_release_111213.pdf.

5. University of California at Santa Barbara. The American Presidency Project: Message to the Senate Transmitting the Single Convention on Narcotic Drugs, 1961. Available at: https://www.presidency.ucsb.edu/documents/message-the-senate-transmitting-the-single-convention-narcotic-drugs-1961.

6. See: The Controlled Substances Act (CSA): A Legal Overview for the 118th Congress. Congressional Research Service [Report R45948]. January 2023; available at: https://crsreports.congress.gov/product/pdf/r/r45948

7. https://twitter.com/nys_cannabis

8. White Paper on Marijuana Dispensaries by the California Police Chiefs Association Task Force on Marijuana Dispensaries, pages 8-11; http://citeseerx.ist.psu.edu/viewdoc/download;jsessionid=8430B99C537AE70A5BAF7C32D284FE24?doi=10.1.1.178.9186&rep=rep1&type=pdf;

Memorandum from Chief David Livingston, Concord California Police Department, to the Mayor and Council Members, August 29, 2003

9. Letter from Keith B. Nelson, Esq. Principal Deputy Assistant Attorney General, US Department of Justice to the Hon. John Conyers, Chairman US House Committee on the Judiciary, July 25, 2008;

See also: https://www.businessinsider.com/dea-complains-about-marijuana-2016-8

10. https://internationalhighlife.com/thc-crystals-pure-thc/

11.
https://www.hhs.gov/surgeongeneral/reports-and-publications/addiction-and-substance-misuse/advisory-on-marijuana-use-and-developing-brain/index.html

12.
https://www.fda.gov/consumers/consumer-updates/what-you-need-know-and-what-were-working-find-out-about-products-containing-cannabis-or-cannabis

https://www.fda.gov/news-events/public-health-focus/warning-letters-and-test-results-cannabidiol-related-products

https://www.fda.gov/consumers/consumer-updates/what-you-should-know-about-using-cannabis-including-cbd-when-pregnant-or-breastfeeding

https://www.fda.gov/consumers/consumer-updates/some-medicines-and-driving-don't-mix

FDA Issues Warning Letters to Companies Illegally Selling CBD and Delta-8 THC Products
https://www.fda.gov/news-events/press-announcements/fda-issues-warning-letters-companies-illegally-selling-cbd-and-delta-8-thc-products

Lung Injury Update: FDA Warns Public to Stop Using Tetrahydrocannabinol (THC)-Containing Vaping Products and Any Vaping Products Obtained Off the Street
https://www.fda.gov/safety/medical-product-safety-information/lung-injury-update-fda-warns-public-stop-using-tetrahydrocannabinol-thc-containing-vaping-products

Five Things to Know about Delta-8 Tetrahydrocannabinol – Delta-8 THC
https://www.fda.gov/consumers/consumer-updates/5-things-know-about-delta-8-tetrahydrocannabnol-delta-8-thc

Vaping Illness Update: FDA Warns Public to Stop Using Tetrahydrocannabinol (THC)-Containing Vaping Products and Any Vaping Products Obtained Off the Street
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