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TESTIMONY OF THE DRUGS AND THE LAW COMMITTEE AND THE HEALTH LAW COMMITTEE

MEDICAL MARIJUANA LEGISLATION ASSEMBLY STANDING COMMITTEE ON HEALTH

Wednesday, December 18, 10:00 A.M. Nassau County Legislative Chambers Theodore Roosevelt Executive & Legislative Building 1550 Franklin Avenue, Mineola, NY

Good morning, my name is Betsy Lambert and I am a member of the New York City Bar's Health Law Committee, which is comprised of attorneys of highly varied backgrounds in the health care field. Thank you to the Assembly Health Committee and Assembly Member Gottfried for providing us the opportunity to testify today. I am joined by Charles Sanford Smith of the Drugs and the Law Committee to express the City Bar's support for pending legislation which would authorize and regulate the sale of medical marijuana in New York. The City Bar first expressed its support for a bill permitting the sale of medical marijuana when it was introduced in the New York Legislature approximately 16 years ago. The City Bar's most recent report, which is included as part of our written testimony, was developed by our two committees with the assistance of the Civil Rights, Land Use and Planning, and Family Court and Family Law Committees. I can sum up the findings of our report simply and as follows: patients who would benefit from and are approved to use medical marijuana should be able to easily gain access to it; specifically, they should be able to receive approved amounts of a quality of medical marijuana that meets standards for growth and sale under the law – a law which we hope will become a reality in New York this year. My colleague will now discuss the pending legislation in greater detail. I am happy to answer any questions at the conclusion of his testimony.

Good Morning. My name is Charles Sanford Smith and I am a member of the City Bar's Drugs and the Law Committee. I will be discussing the legislation which would authorize the sale of medical marijuana in New York.

Medical marijuana is not a hoax or a cover for legalization. With 21 states and the District of Columbia providing safe access to medical marijuana over half of the United States population lives in a state where they have access to medical cannabis. It is time for New York to participate in this process. Medical marijuana prescribed by the proper authority provides relief to millions of individuals all over the country, but not in the great state of New York. This proposed legislation is among the strictest in the country and accomplishes the dual goal of providing relief to suffering patients and protecting the public interest in regulating a controlled substance. As a criminal defense attorney I can attest that the reality of our current legal and enforcement environment permits recreational users of this substance to enjoy its broad availability on the black market, and yet criminalizes its use by the sick and desperate. This disparity in treatment is against the public interest, is bad policy and results in the needless denial of likely beneficial treatment and palliative relief for those who legitimately seek it. New York State has an obligation to allow people with severe debilitating and life threatening conditions to access marijuana legally as a means of alleviating their suffering or improving their condition. This legislation permits it to do so under both medical and governmental oversight.¹

¹ "Report in Support of Legislation Permitting the Production, Distribution and Use of Medical Marijuana in New York State" New York City Bar Association Committee on Drugs and the Law Committee and the Health Committee. Reissued June 2013. Page 15. (Copy attached.)

RECOMMENDATIONS FOR THE BILL

The City Bar supports the pending legislation to legalize medical marijuana in New York – currently, bill number A6357-A in the Assembly and S4406-A in the Senate. In addition to our support, we make the following comments for your consideration:

First, the "A" version of the bill contains several amendments that we believe are overly restrictive. For example:

- The deletion of conditions for which a patient may be certified is overly restrictive and should be removed from the bill.
- The limit of 10 manufacturers for the first 2 years is arbitrary and should be removed from the bill. It is impossible to estimate the potential number of patients in New York State. In a recent study by outgoing comptroller John Liu it was estimated that more than 100,000 residents of New York City could benefit from the use of marijuana.² The entire state of Colorado has approximately 112,862 patients.³ Thus, limiting the number of manufacturers to 10 would make it virtually impossible to keep up with the demand of just the New York City area. This does not take into account the entire rest of the state. The ultimate success or failure of medical marijuana in New York will hinge upon the decisions made in drafting this bill. Creating a weak infrastructure for the program is not good policy or a good use of taxpayer money.
- At the heart of any medical marijuana law is the medical necessity defense. This provision allows individuals who are not certified by the State, but meet all of the

² Regulating and Taxing Marijuana - The Fiscal Impact on New York City. New York City Comptroller August 2013.

³ "Medical Marijuana Statistics," Colorado Department of Public Health and Environment, *available at* <u>http://www.colorado.gov/cs/Satellite/CDPHE-CHEIS/CBON/1251593017044</u> (last visited Dec. 12, 2013).

criteria for certification to use this as an affirmative defense if charged with a marijuana crime. There is no logical reason for not including this provision in the law particularly considering its inclusion in many medical marijuana laws throughout the country.

- We recommend that the labor provision of the bill be removed. Mandating labor related conditions at this time would create barriers to entry and result in confusion and delays in licensing.
- Certification should be limited to physicians and nurse practitioners. Both physicians and nurse practitioners already prescribe medications. Physicians' assistants do not have the ability to prescribe medication without supervision and thus should not be included in this law.
- When the Committees issued an updated position statement in June 2013, there was no consensus on personal cultivation. The Committees, however, felt that the issue was important enough to include some of the arguments from both sides in the position statement. Those who did not support the inclusion of a personal or individual cultivation provision expressed concerns regarding the ability of the authorities to police an individual's backyard. Those in favor of the provision, pointed to states, such as New Jersey and now New Mexico where there have been a number of issues regarding the supply of medical marijuana and therefore would support personal cultivation to alleviate these concerns.

NON-PREEMPTION PROVISION OF THE CONTROLLED SUBSTANCES ACT

The conflict between federal and state law regarding marijuana is extremely complicated and we could likely have hours of hearings on this issue alone. I will attempt to briefly explain the preemption issue with respect to medical marijuana and its importance to the pending legislation.

Pre-emption analysis is complex and involves many different factors, one of which is a determination of whether the legislature intended to occupy the field in which the federal law was passed. The CSA does not purport to expressly preempt state laws in the area of marijuana use; in contrast, it expressly states that no pre-emption is intended unless there is a 'positive conflict' between the state law and the CSA such that 'the two cannot consistently stand together'. Although many people mistakenly believe that there is a positive conflict between state and federal law in the area of medical marijuana, this is not true. Courts have defined the phrase 'positive conflict' narrowly, generally holding that it is only established where (1) compliance with both laws simultaneously is 'physically impossible', or (2) the state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'

Medical marijuana laws do not satisfy either of these prongs: first, a person could comply with both laws simply by avoiding marijuana, and second, state medical marijuana laws do not in any way prevent the federal government from enforcing the CSA.

Pre-emption power is further limited by a concept known as the 'anti-commandeering' principle, which provides that the federal government may not 'commandeer' the state legislative process by forcing states either to enact legislation or to enforce federal legislation.⁴

⁴ The bill in fact contains an "anti-commandeering provision": PHL § 3369a(1) directs state and local law enforcement agencies not to cooperate with or provide assistance to the federal government in enforcing the CSA solely for actions and conduct consistent with the legislation, except pursuant to court order. This provision is consistent with the US Supreme Court's ruling in New York v. United States, 505 U.S. 144 (1992).

Since medical marijuana laws – in particular, this bill– are, in actuality, exemptions from the states' own penal codes, the federal government can no more force the states to repeal these exemptions than it could have forced the enactment of the statutes to begin with.

In sum, the mere permissiveness of any state medical marijuana law does not prevent the federal government from enacting its own laws against the same. Given that the federal government retains the power to enforce its own law in its own jurisdiction, there is no preemption where a state simply allows activity that the federal government prohibits.

Our June 2013 Report – which is attached to our testimony - contains further discussion of these and other salient points of the legislation, including local land use, privacy and family law issues.

CONCLUSION

Throughout the country and world, the suffering of patients is being alleviated by responsible medical marijuana use. The New York City Bar Association believes that New York should join its fellow states and implement a medical marijuana program. The proposed legislation provides for strict regulation of the program, which is important not only to ensure that patients have safe access to proper medicine but also so that the New York medical marijuana industry develops in a tightly regulated environment. We believe that the proposed legislation will implement the proper controls so that marijuana is not diverted into the adult use market. It is time that the New Yorkers who are suffering with debilitating conditions for which medical marijuana can provide relief have safe access to it.

On behalf of the City Bar, thank you for the opportunity to testify today. We are happy to take any questions you might have.

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Report in Support of Legislation Permitting the Production, Distribution and Use of Medical Marijuana in New York State

A.6357-A / S.4406-A

DRUGS & THE LAW COMMITTEE HEALTH LAW COMMITTEE

REISSUED JUNE 2013

THE ASSOCIATION OF THE BAR OF THE CITY OF NEW YORK 42 West 44th Street, New York, NY 10036-6689 www.nycbar.org



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REPORT ON LEGISLATION BY THE COMMITTEE ON DRUGS AND THE LAW AND THE COMMITTEE ON HEALTH LAW

A.6357-A S.4406-A M. of A. Gottfried Sen. Savino

AN ACT to amend the public health law, the tax law, the general business law and the penal law, in relation to medical use of marihuana

THIS BILL IS APPROVED WITH RECOMMENDATIONS

The New York City Bar Association's Committee on Drugs and the Law and its Committee on Health Law (the "Committees")¹ respectfully submit this report examining the legalization of medical marijuana in New York State and providing support for A.6357-A/S.4406-A ("the legislation"), which would create a system for the production, distribution and medical use of marijuana for those citizens who would likely benefit from such use. If feasible, we also recommend the following revisions to the legislation:

- The "A" amendments are unnecessarily restrictive and should be reconsidered;
- only physicians and nurse practitioners should be granted the privilege to certify patients for use of medical marijuana;
- the viability of allowing personal cultivation of medical marijuana should be explored by the Department;
- the legislation should impose confidentiality obligations on all "registered organizations" in order to protect the privacy of certified individuals and their caregivers;
- language should be included to address potential blocking maneuvers undertaken by local land use authorities;

¹The Drugs and the Law Committee studies the dimensions of substance use and abuse and how society deals with those problems, and considers future drug policy goals and objectives. The Health Law Committee is comprised of legal and medical practitioners who pursue the advancement of the public interest and the betterment of the healthcare process. The Committees gratefully acknowledge the assistance of the City Bar's Civil Rights Committee, Land Use and Planning Committee, and Family Court and Family Law Committee.

- the affirmative defense language protecting medical marijuana users who lack registry identification cards should be clarified; and
- the custody and visitation provision should be modified so as to be consistent with the Family Court Act and the Domestic Relations Law.

I. SUMMARY

The legislation legalizes the regulated production, possession, delivery and use of marijuana for medical purposes. It defines the population which may be granted permission for medical use and the circumstances governing such permission. It creates a system governing the production and distribution of medical marijuana and the certification and registration of patients and their caregivers. All aspects of such system are to be substantially regulated by the Department of Health (the "Department"). This well-crafted legislation is complex, and seeks to establish a multi-tiered process for certification, oversight and reporting. It also provides an opportunity for the accumulation of relevant data for further evaluation of the legislation's efficacy. This legislation is among the strictest in the United States. In fact, it is more stringent than the New York laws governing highly dangerous and addictive drugs like morphine, Oxycontin (oxycodone), and Valium (diazepam). This legislation explicitly prohibits consumption in public places and in any location where tobacco may not be smoked. Patients certified to consume medical marijuana must be under the care of specified licensed practitioners. Certified patients and their designated caregivers would be registered with the Department and would only be allowed to possess a limited amount of marijuana for use at a given time. I-STOP procedures have been incorporated in order to safeguard against abuse. Similar to the application process for the licensure of New York State-regulated Article 28 facilities,² organizations that are registered by the Department to cultivate and dispense medical marijuana must undergo a stringent vetting process. In particular, among other criteria to be established by the Department, a registered organization must demonstrate that: (1) its managing officers are of good moral character; (2) it possesses or has the right to use sufficient land, buildings and equipment to properly carry on the activity for which it is licensed; (3) it is able to maintain effective control against the diversion of the marijuana for non-medical purposes; and (4) it is able to comply with all applicable State laws and regulations relating to the activities in which it engages. Registrations must be renewed and continual reporting to the Department is required. The Department is properly authorized to establish the appropriate standards to be imposed on an applicant and an approved registered organization.

II. HISTORY AND CONTEXT OF THE PROPOSED NEW YORK LEGISLATION

A version of the legislation has been introduced in the Assembly every year since 1997 and it last passed the Assembly in 2012.³ An identical bill has been introduced in the Senate every year since 2009 and it has never passed.⁴ The current legislation introduces a regulatory scheme which

 $^{^{2}}$ The Department grants operating certificates to entities for their operation of highly regulated healthcare facilities under Article 28 of the Public Health Law (e.g., hospitals).

³ A.6407, 220th & 221st Sess. (N.Y. 1997-98); A.8082, 222nd & 223rd Sess. (N.Y. 1999-00); A.5878, 224th & 225th Sess. (N.Y. 2001-02); A.5796, 226th Sess, (N.Y. 2003); A.5796-A, 227th Sess. (N.Y. 2004); A.8265, 228th Sess. (N.Y. 2005); A.8265-A 229th Sess. (N.Y. 2006); A.4867-A, 230th Sess. (N.Y. 2007); A.4867-B, 231st Sess. (N.Y. 2008); A.11565 (N.Y. 2010). See Sponsors Memo, A.7347, 235th Sess. (N.Y 2012).

⁴ S.8427, 233rd Sess. (N.Y. 2010).

significantly differs from the law in California. More akin to the comparatively restrictive legislation enacted in New Jersey,⁵ New Mexico⁶ and Rhode Island,⁷ the New York legislation licenses and oversees both the cultivators and dispensers of medical marijuana, and requires registration of patients and their caregivers for the tracking of use. The New York legislation permits only certain organizations to be registered as suppliers. It does not allow individual patients to cultivate marijuana for their own use. Unlike the systems in Rhode Island and New Jersey, the New York law does not place any precise limit on the number of suppliers which the Department can license.⁸ Nonetheless, to ensure access to care and avoid over-saturation, the Department must consider whether the number of registered dispensing organizations in an area will be adequate or excessive to serve reasonably the public need in that area.

III. A BRIEF HISTORY OF THE MEDICAL RESEARCH SUPPORTING MEDICAL MARIJUANA⁹

Between the years 1840 and 1900 more than one hundred articles were published regarding marijuana's potential pharmacological usefulness. In the 20th Century, it had been found to be beneficial as an antiemetic during chemotherapy, for alleviating pain from cancer treatment, for treating glaucoma, for counteracting wasting syndrome in AIDS, for partially alleviating the symptoms of multiple sclerosis and epilepsy, and for controlling muscle spasm in paraplegics and quadriplegics.¹⁰ Throughout the 1970's and 1980's limited research studies relating to the clinical pharmacology of marijuana were conducted under the auspices of many states in coordination with the Federal government.¹¹ Funding for these studies diminished in the mid-1980's, and came to an end in 1992. These studies involved the development of synthetic delta-9-tetrahydrocannabinol (THC) also known generically as dronabinol (Marinol). Delta-9-tetrahydrocannabinol (THC) is the active ingredient in dranabinol and is also a naturally occurring component of marijuana. THC is the principle psychoactive component of marijuana. The synthetic version was produced in pill form in 1985. Nonetheless, these studies yielded data suggesting the potential beneficial effects of marijuana.

⁹ The following paragraph is modified from "Marijuana Should Be Medically Available," the position of the Association of the Bar of the City of New York, drafted by the Committee on Drugs and the Law, dated February 19, 1997.

⁵ The New Jersey Compassionate Use Medical Marijuana Act, N.J. Rev. Stat. 24:61-1 to 16. (2010).

⁶ Lynn and Erin Compassionate Use Act, N.M. 44Stat. Ann. 26-2B-1 to 7 (2007).

⁷ The Edward O. Hawkins and Thomas C. Slater Medical Marijuana Act, R.I. Gen. Laws. 21-28.6-1 to 12 (2006).

⁸ The "A" version of the bill provides that during the first two years after the effective date, the Department may register no more than ten registered organizations that manufacture medical marihuana. This restriction did not appear in the original version of the bill. It raises concerns for the Committees and is discussed further in Point IV(A).

¹⁰ Grinspoon, L. and Bakalar, J., "Marijuana as Medicine - A Pleas for Reconsideration," Journal of the American Medical Association at pp 1875 - 1876 (1995); <u>See generally</u>, Grinspoon, L. and Bakalar J., "Marijuana: The Forbidden Medicine" (Yale Univ. Press 1993). Marijuana was, however, removed from the U.S. Pharmacopeia in 1942. <u>See discussion *infra* n.</u> 23, at 6.

¹¹ Peter Gwynne, "Trials of Marijuana's Medical Potential Languish as Government Just says No," <u>The Scientist</u>, Vol. 9, No. 23, p. 2; Zeese, K. "Medical Marijuana: Effectiveness is Proven By Research." (1997). Online publication at <u>http://ndsn.org/jan97/zeesemm.html</u>. (Last visited February 6, 2013.)

However, smoked marijuana has been demonstrated to be more effective than ingestion and its dosage capable of control.¹²

IV. CURRENT EVIDENCE OF MEDICAL EFFECTIVENESS

After the State of California legalized medical marijuana in 1996, the United States Office of National Drug Control Policy commissioned the Institute of Medicine (IOM), a branch of the National Research Council, to review the existing literature of marijuana's potential medical uses and risks. The IOM's report, published in 1998, concluded that marijuana does have potential medical uses, stating, "nausea, appetite loss, pain and anxiety are all afflictions of wasting, and all can be mitigated by marijuana."¹³ The IOM expressed concern about the health risks of smoking and urged development of "a non-smoked, rapid-onset cannabinoid drug delivery system," but noted that in the meantime, "we acknowledge that there is no clear alternative to people suffering from chronic conditions that might be relieved by smoking marijuana, such as pain or AIDS wasting."¹⁴

In 2008, the American College of Physicians acknowledged that there is documented use of marijuana for certain conditions (e.g., HIV wasting and chemotherapy-induced nausea and vomiting), and suggested that additional research be conducted to clarify marijuana's therapeutic properties and determine standard and optimal doses and routes of delivery.¹⁵ Of particular significance, the State of California established the Center for Medicinal Cannabis Research (CMCR) after the passage of the Compassionate Use Act of 1996 (Proposition 215). Since 1999, CMCR has approved fifteen clinical studies, including seven clinical trials, five of which have been completed. CMCR discovered evidence that cannabis is a promising potential treatment in selected pain syndromes caused by injury or diseases of the nervous system, and possibly for painful muscle spasticity due to multiple sclerosis.¹⁶ Four CMCR-funded studies demonstrated that cannabis has analgesic effects in pain conditions secondary to injury of the nervous system (e.g., spinal cord injury) and disease (e.g., HIV disease, HIV drug therapy). Three of these CMCR studies utilized cannabis as an add-on treatment for patients who were not receiving adequate benefit from a wide range of standard pain-relieving medications. This suggests that cannabis may provide a treatment option for those individuals who do not respond or otherwise respond inadequately to currently available therapies. In addition to nerve pain, CMCR has also supported a study on muscle spasticity in Multiple Sclerosis (MS). Such spasticity can be painful and disabling, and some patients do not benefit optimally from existing

¹⁴ *Id*. p. 8.

¹² Zeese, *supra* at 10-11; Vinciguerra, V. Moore-Terry and Brennan, "Inhalation Marijuana as an Antiemetic for Cancer Chemotherapy," 88 N.Y.S. Journal of Medicine (1988) at pp 525-527; Doblin and Kleiman, "Marijuana an Antiemetic Medicine: A Survey of Oncologists' Experiences and Attitudes," Journal of Clinical Oncology, Vol. 9 (July 1991) at pp 1314 - 1319. Grinspoon and Bakalar, "Marijuana: The Forbidden Medicine" at p. 14.

¹³ Janet Joy, Stanley Watson and John Benson, "Marijuana and Medicine: Assessing the Science Base," National Academy Press (1999) at p. 159.

¹⁵ "Supporting Research into the Therapeutic Role of Marijuana," Position Paper of the American College of Physicians, 2008; <u>See</u> Executive Summary.

¹⁶ I. Grant, M.D., J. Hampton Atkinson, M.D., Andrew Mattison, Ph.D and Thomas J. Coates, Ph. D. Executive Summary, Report to the Legislature and Governor of the State of California, Center for Medicinal Cannabis Research, University of California, San Diego, February 11, 2010, p. 4.

treatments. The results of the CMCR study suggest that cannabis reduces MS spasticity, at least in the short-term.¹⁷

V. THE FEDERAL CONFLICT¹⁸

Currently eighteen (18) states¹⁹ and the District of Columbia have enacted legislation permitting the medical use of marijuana. This has occurred notwithstanding that marijuana is categorized as a Schedule I controlled substance under the Controlled Substances Act of 1970 ("CSA"),²⁰ which does not permit the use of marijuana for any purpose, whether medical or non-medical, and allows for very limited research protocols only.²¹

The New York legislation seeks to protect practitioners from federal and New York State prosecution by allowing them to "certify" that patients may receive a therapeutic or palliative benefit from the use of medical marijuana. This certification would be documented in the patient's medical record. The legislation would not, however, permit practitioners to prescribe or dispense it to their patients.

VI. STATEMENTS OF SUPPORT AND RECOMMENDATIONS

The following presents issues related to the legislation deemed important by our Committees and the factors that underlie our respective support of the legislation. In some instances, the Committees suggest certain bill modifications. In any case, the Committees support enactment of the legislation, particularly if the alternative is no enactment at all.

 20 Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub.L. 91-513, 84 Stat. 1236, enacted October 27, 1970, codified at 21 U.S.C. § 801 et. seq. Schedule I controlled substances are deemed to have (A) a "high potential for abuse, (B) no currently accepted medical use in treatment in the United States and (C) a lack of accepted safety for use under medical supervision." *Id.* § 812(b)(1).

²¹ The United States Pharmacopeia and National Formulary standards of strength, quality, purity, packaging, and labeling are recognized as official and enforced by the Food and Drug Administration pursuant to the Federal Food, Drug and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938), codified at 21 U.S.C. §§ 301-399d (2011). Cannabis had been listed since the Third Edition (1851), but removed by the Twelfth Edition (1942). It is arguable that prohibition of all uses of marijuana, followed by removal from the Pharmacopeia, shows that as a matter of law, not science, marijuana could not have had a "currently" accepted medical use in 1970.

¹⁷ *Id*. p 2.

¹⁸ For a discussion of the federal conflict as it relates specifically to the Bill's anti-commandeering provision, see Point VI(F).

¹⁹ Alaska, Arizona, California, Colorado, Connecticut, Delaware, Hawaii, Maine, Massachusetts, Michigan, Montana, Nevada, New Jersey, New Mexico, Oregon, Rhode Island, Vermont and Washington. Maryland has only an "affirmative defense" provision with a sentencing mitigation for medical necessity. It does not provide any means of access. It is currently considering a comprehensive medical marijuana program as of December 2011. *See* <u>http://www.mpp.org/assets/pdfs/library/Medical-Marijuana-Grid.pdf</u>. (Last visited February 5, 2013.)

A. The "A" Version Amendments

The "A" version of the bill contains several amendments that the Committees believe are overly restrictive. These include (1) deletion of conditions for which a patient may be certified (\$3360(7)), (2) removal of a medical necessity defense available to patients and caregivers who do not have registry identification cards²², (3) an arbitrary maximum of ten manufacturers for the first two years of the program - a cap that is at odds with the Department's duty to "determine the appropriate number of registered organizations to promote reasonable access to medical marihuana" (\$3365(9)), and (4) a requirement that, in order to become registered to do business, an organization must demonstrate that it has "entered into a labor peace agreement with a bona-fide labor organization that is actively engaged in representing or attempting to represent the applicant's employees" (\$3365(1)(a)(iv)); such requirement remains an "ongoing material condition of certification" the breach of which can lead to suspension or termination of registration.

Collectively, these changes reflect an undue constriction of the system to be created. The spirit of the law should be to provide medical marihuana to persons who need it, not to erect hurdles that unduly limit its availability. Prior to these amendments, the Bill already contained sufficient safeguards against diversion and over-saturation. Arbitrarily limiting the number of manufacturers and mandating labor-related conditions will only result in confusion and delays in the licensing and renewal process and create barriers to entry. The movement towards greater restriction is misguided and does not bode well for the success of the program contemplated by the bill. Eighteen states have already legalized medical marihuana and cautionary tales were well considered in drafting the bill. These restrictive amendments are unnecessary and the Committees fear they will interfere with the healthy institution and growth of this program.

B. Practitioner Certification

The current legislation authorizes physicians, physician assistants and nurse practitioners to provide a patient certification (see proposed PHL §3360(12)). Fourteen (14) states²³ and the District of Columbia permit only physicians to make this decision. Four (4) other states²⁴ permit "certifications" from providers other than physicians. *Our Committees take the position that the New York legislation should limit the certification privilege to physicians and nurse practitioners.* Physicians are inarguably exposed to the most rigorous and demanding educational curricula and clinical training and are best equipped to discern potential medical complications that might emerge. Nurse practitioners in New York are specially certified to diagnose and treat certain conditions or patient populations, and like physicians, they are autonomous practitioners authorized to prescribe Schedule II controlled substances on their own. Physician assistants, however, do not have the

²² Rather than delete the affirmative defense in its entirety, the Committees recommend that language be added to the original provision (§3369-a(2)) to the effect that such individuals must otherwise meet all criteria for the registry identification card. Such a change will avoid unintentionally overbroad application.

²³ Alaska, Arizona, California, Colorado, Connecticut, Delaware, Hawaii, Maine, Massachusetts, Michigan, Montana, Nevada, New Jersey and Oregon.

²⁴ New Mexico allows certification by providers licensed to prescribe drugs. Vermont allows certification by physician assistants (PA) and nurse practitioners (NP); Washington adds a Naturopath to the PA and NP; and Rhode Island allows certification by prescribers licensed in Rhode Island or physicians licensed in Massachusetts or Connecticut. See MPP, *supra* note 18.

authority to prescribe Schedule II controlled substances and must always conduct their patient care under the supervision of a physician.

C. The Issue of Personal Cultivation

The New York legislation authorizes a patient to designate a caregiver who will be responsible for obtaining medical marijuana on the patient's behalf. The caregiver must be registered with the Department, and may not care for more than a specified number of patients. The Committees applaud this acknowledgement that individuals who are severely debilitated or battling life-threatening conditions will not always be able to secure marijuana for themselves. However, the Committees are concerned that access to care may be further inhibited for the following primary reasons: (1) dispensaries or sources of medical marijuana may be sparse in certain communities (in particular, medically underserved rural areas), (2) designated caregivers may not be readily available to the isolated aging or disabled population who have no contacts or support, and (3) the cost of procuring medical marijuana may be prohibitive for individuals on a fixed or limited income, particularly the elderly and disabled who are no longer employed.

Although both Committees acknowledge the above concerns, they were unable to reach a consensus on whether amending the legislation to allow for personal cultivation of marijuana is the best way to address them. However, in an effort to inform the debate, we set forth below the substance of the Committees' deliberation.

Those who support amending the legislation to provide an option for personal cultivation point out that, of the states that permit medical marijuana use, only New Jersey, Delaware and the District of Columbia currently do not permit personal cultivation.²⁵ Indeed, the prior 2007 legislation proposed by Assembly Member Gottfried laid out specific criteria for this option.²⁶ States that permit this option include or otherwise provide for the regulatory establishment of specific criteria and controls.²⁷ Supporters believe that the risk of diversion for non-medical use is low because the patient population which will be granted the responsibility for personal cultivation is suffering from severely debilitating and life threatening conditions. These patients will use the limited amount of marijuana permitted to be cultivated under Departmental guidelines for their own treatment and palliative benefit. Additionally, such patients (and their support base) would risk criminal prosecution for illegal diversion. Failing to allow personal cultivation also raises concerns based on the recent experience of

http://www.sec.state.ma.us/ele/ele12/ballot questions 12/full text.htm#three (Last visited, February 14, 2013).

²⁵ Alaska, California, Colorado, Hawaii, Maine, Michigan, Montana, Nevada, New Mexico, Oregon, Rhode Island, Vermont and Washington all permit personal cultivation, with Arizona only allowing it if the patient lives at least 25 miles away from a dispensary. See MPP, *supra* note 18. The most recent medical marijuana program was passed by Massachusetts voters in November 2012. Question 3, the Massachusetts Medical Marijuana Initiative, provides at § 11 that '[t]he Department [of Public Health] shall issue a cultivation registration to a qualifying patient whose access to a medical treatment center is limited by verified financial hardship, a physical incapacity to access reasonable transportation, or the lack of a treatment center within a reasonable distance of the patient's residence.' William Francis Galvin, Secretary of the Commonwealth of Massachusetts, 2012 Information for Voters

²⁶ See A.4867, 230th Sess. (N.Y. 2007).

²⁷ For example, Oregon requires that "grow sites" be registered with the Health Department. Vermont, Michigan and Rhode Island created an ID card program and cultivation must occur in a locked, indoor location (VT) or enclosed locked areas, respectively. New Mexico's regulations allow the Health Department to allow patients to apply for a personal cultivation license. <u>See</u> MPP, *supra* note 18.

the State of New Jersey. In New Jersey, the development and implementation of the regulations under the 2010 medical marijuana law were delayed for over one year, due to the failure of the executive branch to timely promulgate regulations and issue approval to dispensers. During this period of time, qualified patients have been deprived of access to the very treatment regimen that the legislature authorized. Supporters argue that systemic delays should not be permitted to adversely impact severely ill New Yorkers. And, since unlike conventional medications, marijuana can be grown, supporters see no valid reason why it should not be an available option in New York.

Those opposed to personal cultivation express concerns about the practicality of policing individuals' homes and invading privacy, which would make it difficult to assess the risk of excess production and diversion. In addition, the 2013 legislation allows registered producers to dispense medical marijuana directly to caregivers and patients in underserved areas, which alleviates some of the concerns regarding access.

On balance, those who are opposed to the inclusion of personal cultivation in the bill nonetheless believe that the legislation could be amended to require the Department to evaluate the efficacy of personal cultivation of marijuana by patients or caregivers, possibly by implementation of strictly controlled studies or pilot demonstration programs.

D. Diversion

The legislation as originally drafted carefully considered the importance of preventing the diversion of medical marijuana. Its adequate protections include the following: (1) a registered organization may only dispense marijuana to an individual who produces a valid registry identification card and after checking the I-STOP database; (2) the quantity dispensed must be carefully tracked and reported; (3) each registered organization must demonstrate its ability to maintain effective controls against the diversion of marijuana; and (4) any practitioner who certifies a patient for consumption of medical marijuana in bad faith will be subject to potential criminal, civil and licensure proceedings. The Committees agree with Assembly Member Gottfried's assertion that it would be unlikely under this current legislation for anyone to use this highly regulated medical marijuana system to obtain marijuana for recreational use.²⁸ A person would need a practitioner willing to risk his or her license and criminal action to certify in writing that the person has a statutorily defined serious condition that qualifies for use of marijuana, with the full awareness that the patient will file the practitioner's and the patient's name and address with the State and then formally access the drug from a State-licensed dispenser which requires even more paperwork and reporting.²⁹ For these reasons, the Committees believe that the increased restrictions contained in the "A" version of the bill are unnecessary.

E. Privacy

The draft legislation limits the types of entities that can be certified by the Department as "registered organizations" for the purpose of securing and dispensing medical marijuana. Only a pharmacy, a state-licensed Article 28 facility, the state or local health department or a not-for-profit

²⁸ Testimony by Assembly Health Committee Chair Richard N. Gottfried, New York City Council Hearing, Friday, November 18, 2011, <u>http://assembly.state.ny.us/mem/Richard-N-Gottfried/story/45107/</u>. (Last visited February 6, 2013).

corporation may qualify. By law and regulation, an Article 28 facility and pharmacy are already obligated to maintain the confidentiality of patient identity and information. Unfortunately, while the legislation expressly imposes an affirmative obligation on the Department to maintain the confidentiality of certified patients' names, (see proposed PHL §3363(11)) not-for-profit corporations (other than Article 28 facilities that are not-for-profit) are not subject to this privacy mandate. *It is our Committees' position that the legislation should include language imposing confidentiality obligations on all registered organizations*.

F. Local Land Use Issues

The Committees regard medical marijuana dispensaries as more akin to drug stores and pharmacies, in operation and land use impacts, than retail outlets selling recreational substances such as alcohol and tobacco. The Committees believe that medical marijuana dispensaries should be allowed to site "as-of-right" as opposed to going through a process at the local level that, at best, might unduly delay the public's ability to access medical treatment and, at worst, might be motivated by a desire to thwart the establishment and delivery of medical marijuana altogether. It is our position that the interests of a locality cannot be permitted to trump the State's right to create access to medical marijuana treatment, once that need has been established. In that vein, we propose certain modifications to the Bill in order to protect the State's interest in seeing that the goals of the Bill are fully carried out.

Background

Local zoning approval for a particular use can be granted as-of-right or by "special use permit". As-of-right permits are ministerial. As-of-right means that the local authority has determined that the use should be allowed in certain zoning districts (e.g., commercial, but not residential) through the issuance of a permit from the local Department of Buildings ("DOB"), with no exercise of discretion. The DOB would issue the permit, based on compliance with floor area, yard, height and other "bulk" or "area" regulations specified in the zoning ordinance. By way of analogy, in New York City, pharmacies and drug stores are permitted as-of-right.

Special use permits are discretionary. When a local authority requires that a use be allowed by special permit only, it has determined that such use is appropriate in certain zoning districts, but that the use has certain potential negative impacts which necessitate a public review and hearing, prior to the issuance of the special permit by the local zoning board or planning commission. The zoning ordinance will specify certain requirements and findings that need to be met before the special permit can be issued.

The Committees believe that duly registered medical marijuana dispensaries should be granted permits to site as-of-right. This would mean that, in New York City at least, they would be allowed to site without need for a zoning variance or special permit in practically all commercial zoning districts.³⁰ Any criteria relevant to land use impacts, for instance, signage or square footage, could be written into the local zoning ordinance, giving the permitting agency a measure of control for issuing as-of-right permits. As an initial matter, however, the local authority should determine whether such controls are appropriate and would in fact mitigate potential impacts. If such a determination is made,

³⁰Other localities might grant as-of-right permits under different procedures.

the requirements should be specified, in quantifiable terms, in the law and capable of being interpreted by the permitting agency without discretion. Since dispensaries, similar to pharmacies, dispense drugs for consumption off-site (indeed, the legislation specifically prohibits the consumption of medical marijuana in public places and anywhere where tobacco cannot be smoked), there may in fact be no reasonable basis for imposing special siting criteria for this use.

Suggested Bill Modifications

In order to ensure that the primary purpose of the Bill - i.e., access to medical marijuana treatment within a regulatory framework - is not thwarted at the local level, the Committees propose the following proactive solutions for consideration:

- **Declaration.** An express declaration or finding can be included in the legislation that duly registered medical marijuana dispensaries do not pose a special harm or danger to communities or local governments.
- Non-Discrimination Provision. A prohibition against discrimination by government agencies and quasi-governmental authorities (such as zoning boards) can be included in the legislation, to ensure that medical marijuana dispensaries are treated in a manner consistent with other comparable commercial land uses when issuing a permit or enacting ordinances, laws and regulations.
- A Robust Rulemaking Process. The Legislature should consider issues that might concern the localities, and work with the State Department of Health to implement regulations to ameliorate those concerns, as it has done for other pharmaceuticals. An example of this is the state controlled substance regulation of methadone clinics, in which the issues of signage, diversion, security, and the concerns of the federal government are incorporated in OASAS's regulation of clinics, or regulations governing pharmacies, which are must less restrictive, but still tightly govern the handling of narcotics.
- **Limited Preemption.** The legislation can include two pre-emption clauses which would serve to invalidate local ordinances, laws and regulations to the contrary: (1) pre-emption of complete exclusionary provisions (whether express or implied), and (2) pre-emption of provisions which otherwise prohibit the dispensation of Schedule I Controlled Substances to the extent such applies to medical marijuana within a Statelicensed dispensary.

The Committees recognize that the State has the power to create a blanket preemption of all local authority in this matter, but views these more aggressive measures as too controversial, disempowering, and, in fact, not appropriately deferential to the true needs of certain local interests.

G. The Anti-Commandeering Provision of the Bill

We support proposed PHL §3369-a(1) of the bill which directs state and local law enforcement agencies not to cooperate with or provide assistance to the federal government in enforcing the CSA³¹ solely for actions and conduct consistent with the legislation, except pursuant to court order. Just as the CSA does not preempt New York from enacting a law to permit the production and dispensing of medical marijuana, it does not preempt New York from enacting an anti-commandeering provision such as this one. This provision adheres to 10th amendment principles while recognizing that the federal government is free to use its own resources, if it so chooses to enforce the CSA in New York.

Although the federal government is free to execute and enforce the CSA under the powers derived under the Commerce Clause³², it is the view of the Committees that the CSA does not preempt enactment of the Bill.³³ We agree with the holding in the recent case of *White Mountain Health Center v. County of Maricopa, CV 2012-053585 (Sup. Ct. Ariz. December 3, 2012)*, in which the court upheld Arizona's medical marijuana law and stated:

"Clearly, the mere State authorization of a very limited amount of federally proscribed conduct, under a tight regulatory scheme, provides no meaningful obstacle to federal enforcement. No one can argue that the federal government's ability to enforce the CSA is impaired to the slightest degree. Indeed, the United States Supreme Court has been unequivocal on this point."³⁴

The Legislature is well within its rights to enact an anti-commandeering provision such as the one included in the Bill. In *New York v. United States*, the Supreme Court determined that the federal government cannot commandeer the legislative process of the states.³⁵ In *Printz v. United States*, the

³³ The CSA does not purport to expressly preempt state laws in the area of marijuana use. Rather, the CSA states: "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 (Emphasis added.) Thus, the CSA preempts only those state laws that create a positive conflict with the federal law, which is not the case here.

³⁴ <u>Citing</u> Gonzales v. Raich, supra note 30; <u>but see</u> Emerald Steel Fabricators, Inc. v. Bureau of Labor and Industries, 230 P3d 518 (Or. Sup. Ct. 2010). For a full discussion of preemption issues surrounding medical marijuana laws, <u>see</u> Garvey, Todd, March 6, 2012, Medical Marijuana: The Supremacy Clause, Federalism, and the Interplay Between State and Federal Laws, CRS Report for Congress, Congressional Research Service, <u>available at</u> <u>http://assets.opencrs.com/rpts/R42398_20120306.pdf</u>; Mikos, Robert A., December 12, 2012, On the Limits of Federal Supremacy When States Relax (or Abandon) Marijuana Bans, <u>available at http://www.cato.org/publications/policy-</u> analysis/limits-federal-supremacy-when-states-relax-or-abandon-marijuana-bans. (Last visited February 20, 2013).

³⁵ *New York v. United States*, 505 U.S. 144 (1992) (striking down federal law that required the state to create its own laws disposing of radioactive waste within its borders).

³¹ <u>See *supra* n. 19</u>. The CSA was enacted to control illicit trafficking and to regulate legitimate uses of psychotropic substances in this country.

³² *Gonzales v. Raich*, 545 U.S. 1 (2005) (federal government can prohibit under federal law the local cultivation and use of marijuana that is legal by state law, even when that cultivation and use is intrastate and for a medical purpose).

court ruled that a state cannot be forced to use its own state actors to enforce any federal law.³⁶ Therefore, the federal government cannot force any state to pass any law that mandates enforcement of the CSA, and the federal government cannot force state or local law enforcement personnel to investigate, arrest or prosecute any alleged violations of the CSA.³⁷

In sum, the mere permissiveness of any state medical marijuana law, which is in essence a decriminalization of a federal crime, does not prevent the federal government from enacting its own laws against the same. Given that the federal government retains the power to enforce its own law in its own jurisdiction, there is no preemption where a state simply allows activity that the federal government prohibits.³⁸ It simply puts the burden of enforcement on the resources of the jurisdiction desiring the enforcement. As such, the anti-commandeering provision simply makes clear that federal law enforcement authorities cannot require or expect assistance from state law enforcement personnel.

H. Non-Discrimination Provision

The bill provides that schools, employers or landlords cannot discriminate against a patient or designated caregiver solely for their status as a patient or caregiver involved with medical marijuana (see proposed PHL §3369-a(4)). Since this provision is not within the confines of the Human Rights Law, a question of enforcement arises. *Therefore, the Committees recommend that explicit private right of action language be included.*

I. Custody and Visitation Provision

Proposed Section 3369-a(6) of the bill provides: "A person shall not be denied custody or visitation of a minor for acting in accordance with this title unless the person's behavior is such that it creates an unreasonable danger to the minor that can be clearly articulated and substantiated." The intent of section 3369-a(6) appears to be to prevent the medically-approved use of marijuana from being a *per se* bar to an individual having custody of or visitation with a minor, rather than to change the standards that are ordinarily applicable in custody, visitation and child protective proceedings. We therefore propose that it be modified to read:

"A person shall not be denied custody or visitation of a minor <u>for the</u> <u>sole reason that he or she has acted</u> [for acting] in accordance with this title; <u>however</u>, nothing herein is meant to or should be construed as <u>limiting the application of Domestic Relations Law Section 240(1) or</u> <u>Family Court Act Article 10</u> [unless the person's behavior is such that it

³⁶ *Printz v. United States*, 521 U.S. 898 (1997) (striking down federal law that required state police to conduct background checks on prospective handgun purchasers).

³⁷ <u>See also Mikos</u>, *supra* n. 32 at 10 ("[T]he anti-commandeering rule constrains Congress's power to preempt state law in at least one increasingly important circumstance – namely, when state law simply permits private conduct to occur – because preemption of such a law would be tantamount to commandeering.").

³⁸ <u>See also</u> Garvey, *supra* n. 32 at 9 (<u>citing</u> *Wyeth v. Levine*, 555 U.S. 555 (2009); *Barnet Bank v. Nelson*, 517 U.S. 25 (1996)). Ironically, it is arguable that it is the *federal government*_that should defer to a state's recognition of medical uses for marijuana under the well-settled principle that the practice of medicine is a matter best reserved to the states. *Gonzales v. Oregon*, 545 U.S. 1 (2005).

creates an unreasonable danger to the minor that can be clearly articulated and substantiated]."

The use of medical marijuana should neither be a *per se* bar to custody or visitation, nor should it trump the "best interests of the child" standard as articulated in existing law. In New York State, custody and visitation determinations are governed by DRL Section 240(1), which states that custody orders shall be entered "as, in the court's discretion, justice requires, having regard to the circumstances of the case and of the respective parties and to the best interests of the child and subject to the provisions of subdivision one-c of this section." A parent can only be displaced as a custodian by a non-parent if a two-pronged test is met: (1) a showing of extraordinary circumstances which overcomes the presumption of a natural parent's superior right to custody;³⁹ and (2) a determination of what is in the best interests of the child. A myriad of factors are encompassed in the best interests standard: the relative fitness of the respective parties; ability to provide for the child's emotional and intellectual development; quality of the home environment; the parental guidance provided by each party; the financial ability to provide for the child; and the presence of siblings. The age and desires of the child are considered, but are not determinative.

We can also infer that proposed §3369-a(6) is meant to protect against an individual who uses medical marijuana being found *per se* neglectful of a child (in which case custody of the child could be at risk). Family Court Act Article Ten is the statutory framework for child neglect proceedings. Once a child neglect case is filed, the Family Court makes an initial determination whether a child should remain with a parent pending a fact finding hearing. The standard governing this determination is whether removal is necessary to "avoid imminent risk to the child's life or health."⁴⁰ In making this determination, the Court considers whether "continuation in the child's home would be contrary to the best interests of the child and where appropriate, whether reasonable efforts were made" to eliminate the need for removal of the child.⁴¹

Under the Family Court Act, a "neglected child" is defined as, among other things, a child "whose physical, mental or emotional condition has been impaired or is in imminent danger of becoming impaired as a result of the [parent's] failure...to exercise a minimum degree of care....in providing the child with proper supervision and guardianship, ...by misusing a drug or drugs[.]"⁴² Specifically concerning drug use, in order to establish a *prima facie* case of neglect, the government must prove that the parent "repeatedly misuses a drug or drugs...to the extent that it has or would ordinarily have the effect of producing in the user thereof a substantial state of stupor, unconsciousness, intoxication, hallucination, disorientation, or incompetence, or a substantial impairment of judgment, or a substantial manifestation of irrationality."⁴³ If after a fact finding trial a child is adjudicated neglected, the court must make a determination of whether "continuation in the

⁴³ *Id*.

³⁹ A showing of extraordinary circumstances is based on a demonstration of unfitness, neglect, abandonment, surrender or other extraordinary circumstances. <u>See Bennett v Jeffreys</u> 40 N.Y.2d 543 (1976); *Dickson v Lascaris*, 53 N.Y.2d 204 (1981); *Merritt v Way*, 58 N.Y.2d 850(1983).

⁴⁰ Family Court Act §§ 1027(b)(i), 1028(a).

⁴¹ Family Court Act §§ 1027(b)(ii), 1028(b).

⁴² Family Court Act § 1012(f)(i).

child's home would be contrary to the best interests of the child."⁴⁴ The statute does not specifically address marijuana use.

VII. CONCLUSION

The Committees on Drugs and the Law and Health Law of the New York City Bar Association agree that New York State should legalize access to marijuana for patients who need it. This proposed legislation is among the strictest in the country and accomplishes the dual goal of providing relief to suffering patients and protecting the public interest in regulating a controlled substance. Furthermore, the reality of our current legal and enforcement environment permits recreational users of this substance to enjoy its broad availability on the black market, and yet criminalizes its use by the sick and desperate. This disparity in treatment is against public interest and results in the needless denial of likely beneficial treatment and palliative relief for those who legitimately seek it. New York State has an obligation to allow people with severe debilitating and life-threatening conditions to access marijuana legally as a means of alleviating their suffering – and this legislation permits it to do so under both medical and governmental oversight.

The Committees greatly appreciate the time given to read and consider these comments and recommendations and together urge the ultimate passage of this legislation.

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⁴⁴ Family Court Act §§ 1052(b).