For the Record

Kevin A. Sabet, Ph.D.
Director, University of Florida Drug Policy Institute,
Department of Psychiatry, Division of Addiction Medicine
Director, Project SAM (Smart Approaches to Marijuana)
Author, *Reefer Sanity: Seven Great Myths About Marijuana*

Before the New York City Council
October 22, 2013

Written Testimony
"States' Medical Marijuana Protection Act"

Distinguished members of the Committee, thank you for providing me with the opportunity to submit written testimony on the subject of the States' Medical Marijuana Protection Act, which seeks to reclassify marijuana.

I have studied, researched, and written about drug policy, drug markets, drug prevention, drug treatment, criminal justice policy, addiction, and public policy analysis for almost 18 years. Most recently, from 2009-2011, I served in the Obama Administration as a senior drug policy advisor. I am currently the co-founder, with former Congressman Patrick J. Kennedy, of Project SAM (Smart Approaches to Marijuana). I am also the author of *Reefer Sanity: Seven Great Myths About Marijuana* (NY: Beaufort).

I am delighted to share with you my perspective, based on evidence and experience, on this topic. I address this at length in a recent Law Review article I wrote called "Much Ado About Nothing" which may be found online, and will summarize its main points here.

Rescheduling marijuana is a distracting issue that does not get at the core of using marijuana for its medicinal value, namely because:

- **Rescheduling marijuana would do nothing to allow marijuana to be properly prescribed at pharmacies.**
- **Rescheduling marijuana would do nothing to lessen penalties for marijuana use.**
- **Rescheduling marijuana would not legalize "medical marijuana dispensaries" or the home cultivation of marijuana.**
- **Rescheduling marijuana would serve as a meaningless token and distract from issues of real significance.**

The reason marijuana hasn't been rescheduled is because *products of herbal marijuana have "no currently accepted medical use" in the U.S., which is part of the legal definition of Schedule I in the Controlled Substances Act.* This criterion requires more than the fact

that the voters or legislators of a certain number of states have allowed the use of marijuana for medical purposes; more than reports of individual cases highlighted by the media; it requires rigorous evidence that a product is safe, properly tested and manufactured, and actually works for a particular medical condition.

By contrast, Schedule II substances do have a currently accepted medical use in the U.S. or a currently accepted medical use with severe restrictions (and, like Schedule I drugs, a high potential for abuse). Schedule III-V substances have accepted medical usefulness and lower abuse potential than Schedule II drugs.

More importantly, regardless of the schedule, **a substance may be prescribed by physicians and dispensed by pharmacists only when incorporated into specific FDA-approved products. That is why Schedule II opioid products can be obtained in pharmacies by prescription, but opium itself, despite being in Schedule II, is not prescribed.** The DEA schedules **classes** of drugs, and the FDA approves **specific products** containing those drugs. Schedule II (or III-V) status alone is not enough to make herbal marijuana, or any other a substance, available by prescription. Only FDA approval can do that.

So why doesn't whole marijuana have a "currently accepted medical use"? There have not been scientific studies, of adequate size and duration, showing that a product comprised of whole marijuana (smoked or vaporized or otherwise ingested) has medicinal value. FDA has never approved crude plant material as a prescription medicine, partly because there is no well-validated way to administer it in defined doses and without any toxic by-products. FDA has also never approved medicines that are smoked (though it can be vaporized or eaten, by and large herbal marijuana is almost always smoked). However, there have been studies showing that components or constituents within marijuana have medical value. This is where many people get confused. *That is why both statements "marijuana has no medical value" and "marijuana is a medicine" are both untrue.*

Which components within marijuana have accepted medicinal value? At least one, and maybe even more than that. Right now, a capsule, Marinol, entirely containing lab-made THC, the active ingredient in marijuana (e.g. what gets you high) is in Schedule III and widely available (though not often prescribed) at pharmacies. Marinol was approved first for nausea/vomiting from cancer chemotherapy and again during the height of the AIDS epidemic, specifically for people who could not eat (scientists have long known that THC boosts appetite). THC has also been tested (but not yet approved) as an analgesic - meaning it helps lessen severe pain (like the pain associated with cancer).
But we know that THC isn't the only interesting component in marijuana. Recently scientists have discovered that CBD (Cannabidiol) has powerful anti-seizure and other therapeutic properties. CBD does not get you high and barely exists in the modern marijuana found on the street today. Some US state-sanctioned medical dispensaries do

offer expensive, specially grown strains of smoked/ingested/extracted (in an oil, for example) marijuana with very high levels of CBD (and low levels of THC - not enough to get you high). However, these products have not been properly tested and standardized, and can vary significantly in composition and purity from batch to batch. Dispensaries do not collect reliable data on whether or not (and to what extent and in what ways) patients are benefitted or harmed. That is why, 17 years after the first California initiative, neither marijuana nor any of the products offered in these dispensaries has developed into a true medication that is widely accepted by the medical profession.

Is it possible to make a medicine from a whole marijuana extract? Absolutely. Almost two-dozen countries have approved a product comprised of an extract of marijuana that mainly contains CBD and THC called Sativex. Sativex is an oral spray that does not get you high, and has been shown to have positive effects on spasticity associated with MS and severe cancer pain. Will the U.S. allow research to take place with such a product? Again, absolutely. Sativex is currently being studied in late-stage Phase III trials in over 40 research sites with the approval of the FDA and the DEA.

So where does that leave us? While marijuana does not meet criteria for a Schedule II or lower drug, that doesn't mean we can't harness the medicinal value contained within it. We do this with several drugs today, including a drug like GHB (a powerful Schedule I drug associated with date-rape). A product called Xyrem is not Schedule I and is based on the active ingredient in GHB, prescribed for narcolepsy and loss of muscle control.

Rescheduling marijuana may appear to be a victory for marijuana advocates – but in actuality would be a meaningless illusion since it would do nothing to change marijuana's non-placement in the pharmacopeia or even decrease marijuana-specific penalties for use or trafficking.

Marijuana's components have medicinal value, though, like the Institute of Medicine (IOM) concluded in the most sweeping independent review of this issue, its future as a medicine does not lie in its smoked or ingested raw form. Rather than promote a non-accountable system of "dispensaries" run by non-medical staff with ties to the underground economy and who sell marijuana to anyone with a pulse, groups like Project SAM (Smart Approaches to Marijuana) are trying to work with federal and state agencies to ensure we can study marijuana's medicinal value and develop pharmacy-obtainable medications that are safe and effective, with reliable dosage and known composition.

What about patients who are truly sick and dying? SAM has advanced a new idea: While we wait for properly-standardized marijuana-based products to obtain FDA-approval, we could enroll the seriously ill into carefully structured special access programs, as long as they understand potential risks, so they can get these promising products today (including

children with uncontrollable seizures). Such programs have been used in the past by NIH, and FDA currently has regulations that permit them.

I strongly urge the New York City Council to avoid being sidetracked by a resolution that can have no impact and instead stick to the science. And the science is clear: though smoked or ingested marijuana is not medicine, and though rescheduling marijuana would only serve as a symbolic victory for advocates, products based on marijuana show considerable medical promise. The Council should encourage the US National Institutes of Health to speed up such research, and in the meantime enroll truly seriously ill patients with cancer, MS, and other conditions in special access programs to ease their pain and suffering.

FOR THE RECORD

Testimony of:
Mary Beth Morrissey, Esq.
Co-Chair, Policy Committee of Public Health Association of New York City

Submitted to: New York City Council Committees on Health; Mental Health, Developmental Disability, Alcoholism, Drug Abuse and Disability Services

Re: Resolution No. 1260-A
Wednesday, October 23, 2013

Thank you, members of the Committees on Health; Mental Health, Developmental Disability, Alcoholism, Drug Abuse and Disability Services; and Subcommittee on Drug Abuse for inviting our testimony. On behalf of the Public Health Association of New York City and the Drug Policy Alliance, I am pleased to testify in support of Res. No. 1260-A, calling on the United States Congress to pass and the President to sign the States' Medical Marijuana Patient Protection Act, which seeks to reclassify marijuana as other than a Schedule I or Schedule II substance.

The bill, which this resolution calls on Congress to pass, has bipartisan support. It would reschedule marijuana below Schedule II under the Controlled Substances Act (CSA) to recognize its therapeutic properties and allow states to set their own medical marijuana policies without federal interference. As you know, marijuana is currently listed at Schedule I under the CSA, meaning it is considered to be a substance with a high potential for abuse and no accepted medical use.

However, since 1996, 20 states and the District of Columbia have passed laws legalizing the use of medical marijuana for qualifying patients, and it is estimated that hundreds of thousands of Americans suffering from debilitating conditions find significant relief from the use of medical marijuana. The Compassionate Care Act – A.6357B (Gottfried) / S.4406A (Savino) – which would create a carefully regulated medical marijuana program for seriously ill patients in New York, is currently pending before the legislature in Albany. The Public Health Association of New York City has voted in support of this bill. These programs, as well as the New York bill, enjoy overwhelming public support, with polling consistently finding that more than three out of four Americans endorse medical marijuana.

H.R. 689 would prevent federal authorities from using the CSA or the Federal Food, Drug, and Cosmetic Act to restrict activities related to medical marijuana in states where it is legal, ensuring the ability of states to provide legitimate, regulated access to medical marijuana for qualifying patients. The Obama administration recently clarified its position on state marijuana laws, directing the US Attorneys General to not interfere with state laws that met federal interests, but this position has not been codified into law, leaving states in a somewhat ambiguous legal position. The climate of fear and legal barriers that have resulted from the federal government's position harms patients, making it much more difficult for them to obtain reliable, safe supplies of the medicine they need from a regulated system. It has also had a significant chilling effect on the implementation of state-level medical marijuana programs. Last year, Rhode Island Gov. Lincoln Chafee, former Washington Gov. Christine Gregoire, Colorado Gov. John Hickenlooper and Vermont Gov. Peter Shumlin, petitioned the federal government to reschedule marijuana to allow for medical use.

Every independent commission to examine marijuana policy has concluded that its harms have been greatly exaggerated – including the 1944 LaGuardia Report, President Nixon's 1972 Schaffer Commission report, and the 1999 Institute of Medicine report commissioned by the Office of National Drug Control Policy. Despite the plethora of scientific evidence establishing marijuana's medical safety and efficacy, researchers seeking to conduct further research on its therapeutic benefits find themselves unable to access marijuana to carry out their studies. This is in large part due to the monopoly that the National Institute on Drug Abuse (NIDA) maintains on access to marijuana for research. NIDA's mission is to combat drug abuse and addiction, which is at odds with the interests of researchers who seek to obtain marijuana to conduct research on its medical properties. We applaud your goal to resolve this conflict, as H.R. 689 would transfer control over access to marijuana for medical research to an entity whose primary purpose is not to examine the addictive properties of substances.

It is clear that federal law must be updated to allow states to individually implement a medical marijuana policy and do what is best for their critically ill residents without fear of federal intervention. H.R. 689 would ensure that medical marijuana patients and providers in compliance with state or local laws no longer have to live in fear of federal authorities. Once passed, this important legislation will acknowledge what patients, doctors, researchers and scientists have been saying for years: marijuana has therapeutic and medicinal benefits. We applaud the New York City Council for bringing Resolution 1260-A forward and urge its swift passage. Thank you for your leadership on this important issue.

Marijuana Policy Project
P.O. Box 77492 • Capitol Hill
Washington, D.C. 20013
p: (202) 462-5747 • f: (202) 232-0442
info@mpp.org • www.mpp.org

October 23, 2013

The New York City Council Committee on Health jointly with the Committee on Mental Health, Developmental Disability, Alcoholism, Drug Abuse and Disability Services and Subcommittee on Drug Abuse.

RE: Proposed Res. No. 1260-A - Resolution calling on the United States Congress to pass and the President to sign the States' Medical Marijuana Patient Protection Act, which seeks to reclassify marijuana as other than a Schedule I or Schedule II substance.

Good morning everyone,

I'd like to start by pointing out that no one at MPP has ever seen or heard of a hearing like this one. The fact that the New York City Council is urging the federal government to take action on medical marijuana when this state still has no medical marijuana law in place is quite unusual. But then again, this city is not really like any other, so we are encouraged by the very existence of this hearing and would like to thank the committee for raising the issue of reclassifying marijuana.

Federal marijuana policy is trapped in absurd circular logic. Officials argue that marijuana must be kept illegal because it is a "dangerous" Schedule I drug. They refuse to move it out of Schedule I, claiming that there is no evidence that it has medical value. They refuse to allow private entities to cultivate marijuana for research to demonstrate that it has medical value. And they set up endless obstacles for any researchers who hope to conduct potentially favorable studies with the marijuana that is grown and controlled by the federal government. No research, no evidence, no rescheduling.

Marijuana research, it seems, is a victim of marijuana politics. Under federal law, a drug is considered most harmful — and placed in the most restrictive category, Schedule I — if it has "no currently accepted medical use." Although marijuana was listed as a medicine in the U.S. Pharmacopoeia before its prohibition and was widely used for dozens of conditions, Congress temporarily placed it in Schedule I in 1970, pending the outcome of a government study. The study, produced by a national commission on drug abuse, ultimately concluded that marijuana's harmful effects were so limited for light and moderate users that it should not even be a criminal offense to use it. But its status as a Schedule I drug has not changed.

Advocates have been working toward a change since 1972, when the first petition to reschedule marijuana was filed with the Bureau of Narcotics and Dangerous Drugs, the predecessor of the Drug Enforcement Administration. After many refusals to act and a few court rulings, the DEA finally initiated hearings on rescheduling in 1986 — 14 years after the first filing.

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Washington, D.C. 20013
p: (202) 462-5747 • f: (202) 232-0442
info@mpp.org • www.mpp.org

These hearings led to an opinion in 1988 by the DEA's chief administrative law judge, Francis Young, who wrote: "Marijuana, in its natural form, is one of the safest therapeutically active substances known to man. . . . It would be unreasonable, arbitrary and capricious for DEA to continue to stand between those sufferers and the benefits of this substance in light of the evidence in this record." He concluded that the provisions of the Controlled Substances Act "permit and require" the transfer of marijuana from Schedule I to a less restrictive category. Yet the DEA administrator did not reclassify marijuana. Since that time, the agency has denied two other rescheduling petitions, most recently in July 2012.

It is bad enough that the DEA has repeatedly ignored existing evidence regarding marijuana's therapeutic value in order to maintain the drug's Schedule I status. But both the DEA and NIDA have taken further steps to block any new evidence from being produced. Most notably, the DEA has refused for 10 years to grant a license to the University of Massachusetts to cultivate marijuana for FDA-approved research, providing a privately funded alternative source to NIDA's marijuana supply. The refusal has occurred despite yet another DEA administrative law judge ruling that the license would be "in the public interest" and should be granted.

The federal government's stance has led to our current state-by-state battles over medical marijuana. We will continue to fight and will add more states to the pro-medical-marijuana side of the ledger. But it will be many years, possibly decades, before marijuana is legal for medical purposes in all 50 states.

In the 20 states that do have medical marijuana laws, there are still conflicts between state and federal law and those conflicts prevent states from effectively implementing and regulating medical marijuana programs. For example:

- Because marijuana remains illegal under federal law, banks and credit card companies refuse to provide services to dispensaries. As a result, they are cash-only businesses and have no place to deposit that cash. This makes these businesses and their employees targets for robbery, and makes it harder for the states to collect tax revenue.

- Doctors cannot prescribe marijuana, and instead "recommend" it. Because a prescription is legally akin to an "order to dispense," prescribing marijuana would be aiding and abetting a violation of federal law. Courts have, however, said doctors have a First Amendment right to discuss the risks and benefits of any substance with their patients. The result is that marijuana is recommended, and states can't regulate it as they would other medications.

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Washington, D.C. 20013
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info@mpp.org • www.mpp.org

- Pharmacies cannot dispense marijuana. They need a DEA license to dispense controlled substances, and would lose that license if they illegally dispensed a schedule I substance like marijuana. As a result, states have to set up dispensaries that are akin to pharmacies with respect to marijuana, but also have to set up a separate, coexisting regulatory enforcement program for dispensaries rather than simply routing dispensation through pharmacies like any other drug.

- Businesses involved in medical marijuana cannot deduct "ordinary business expenses " The IRS tax code prevents taking such deductions if one's business is in trafficking drugs illegal under federal law. This has been interpreted to apply to medical marijuana businesses since it's illegal under federal law. The end result is dispensaries end up getting taxed on gross profits rather than net profits, and many go out of businesses reducing the supply available to legitimate patients.

Obviously, marijuana does have medical purposes and is not as dangerous as heroin or methamphetamines, so science should recognize that. But legally speaking, what's important is that the bill would make the Controlled Substances Act inapplicable to medical marijuana activities that are legal under state law. In other words, it would make those activities legal under federal law in states that allow it. That would allow dispensaries or pharmacies to dispense it, doctors to prescribe it, and businesses to access banking services.

Given the way public opinion is moving (85% support medical marijuana according to Fox News) medical marijuana is inevitable in New York state. New York would be in a much better position to regulate medical marijuana if Congress were to pass legislation like the H.R. 689, the Medical Marijuana Patient Protection Act.

Sincerely,

Kelley Crosson
Development Officer – New York
Marijuana Policy Project
kcrossson@mpp.org
917-699-2915

VOCAL
NEW YORK

October 23, 2013

Testimony by Wanda Hernandez
Chairperson, VOCAL-NY Board of Directors

Re: **Proposed Res. No. 1260-A** – Resolution calling on the United States Congress to pass and the President to sign the States' Medical Marijuana Patient Protection Act, which seeks to reclassify marijuana as other than a Schedule I or Schedule II substance.

Submitted to: New York City Council Committee on Health, Committee on Mental Health, Developmental Disability, Alcoholism, Drug Abuse and Disability Services, and Subcommittee on Drug Abuse.

Thank you for the opportunity to speak with you today. As the Chair of VOCAL-NY's Board of Directors, I am pleased to testify in support of Resolution Number 1260-A, which calls on the United States Congress to pass and the President to sign the States' Medical Marijuana Patient Protection Act, which seeks to reclassify marijuana so that it is no longer a Schedule I or Schedule II substance. As a woman living with HIV and chronic pain conditions, please understand that this is a very personal and important issue for me.

As you know, marijuana is currently listed as a Schedule I under the Controlled Substances Act (CSA), meaning it is considered to a substance with high potential for abuse and no accepted medical use. This contradicts extensive scientific and anecdotal evidence confirming the safety and efficacy of medical marijuana for illnesses ranging from HIV/AIDS, cancer, MS and others. As a woman living with HIV, I have experienced first-hand the effects of medical marijuana in combatting nausea, stimulating appetite and alleviating suffering due to neuropathic pain.

Recognizing the needs of people like me who live with severe and debilitating illness, twenty states and the District of Columbia have already passed laws decriminalizing the use of marijuana for medical purposes. In New York, the Compassionate Care Act – sponsored by Assembly Health Committee Chair Richard Gottfried and Senator Diane Savino – has already passed the Assembly with strong bipartisan support and has support on both sides of the aisle in the Senate. The Compassionate Care Act would provide safe and legal access to medical marijuana for seriously ill and disabled New Yorkers.

Although the Obama administration recently clarified its position on state marijuana laws, directing US Attorneys General to refrain from interference with state medical

marijuana programs, this position is not yet codified into law. This leaves state medical marijuana programs in a legal gray area lacking protection under federal law and creating unnecessary barriers to safe and legal access for patients.

It is vitally important that federal law is updated to recognize the therapeutic benefits of medical marijuana while allowing states to establish their own policies without federal interference. On behalf of VOCAL-NY, I urge you to pass resolution 1260-A to ensure that medical marijuana patients and providers in compliance with state or local laws no longer have to live in fear of federal authorities. Thank you for your consideration and leadership on this important issue.

Contact information:

Anna Saini, VOCAL-NY's Statewide Organizer, is coordinating our medical marijuana advocacy. She can be reached at (646) 409-4164 or anna@vocal-ny.org.

THE COUNCIL
THE CITY OF NEW YORK

Appearance Card

I intend to appear and speak on Int. No. _____ Res. No. 1260-A

☒ in favor ☐ in opposition

Date: 23 Oct 2013

(PLEASE PRINT)

Name: Ruth Liebesman

Address: 30 Wall St, NYC

I represent: Empire State NORML

Address: 56th St, NYC

THE COUNCIL
THE CITY OF NEW YORK

Appearance Card

I intend to appear and speak on Int. No. _____ Res. No. 1260A

☑ in favor ☐ in opposition

Date: 10/23/13

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Name: Mary Beth Morrissey → PHANYC

Address:

I represent: Public Health Association of NYC

Address: 1 University Plaza - HS204, Brooklyn NY 11201

Please complete this card and return to the Sergeant-at-Arms

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I intend to appear and speak on Int. No. _____ Res. No. 1260-A

☒ in favor ☐ in opposition

Date: 10/23/13

(PLEASE PRINT)

Name: KELLEY CROSSON

Address: 375 SOUTH END AVE 8C NYC 10280

I represent: NMPP

Address: 236 Massachusetts Ave NE SUITE 400 Washington DC 2002

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Date: _____

(PLEASE PRINT)

Name: WANDA HERNANDEZ

Address: 684 E 189th ST. BX NY 10458

I represent: VOCAL - NY

Address: 80A 4th AVE ATLANTIC AVE BROOKLYN

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☐ in favor ☐ in opposition

Date: _____

(PLEASE PRINT)

Name: Ari Hoffnung

Address: _____

I represent: NYC Comptroller John Liu

Address: _____

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