



Health Quality Subcommittee

Wednesday, January 25, 2017

9:00 AM – 11:00 AM

Webster Hall (212 Knott)

Richard Corcoran
Speaker

Cary Pigman
Chair

Committee Meeting Notice

HOUSE OF REPRESENTATIVES

Health Quality Subcommittee

Start Date and Time: Wednesday, January 25, 2017 09:00 am
End Date and Time: Wednesday, January 25, 2017 11:00 am
Location: Webster Hall (212 Knott)
Duration: 2.00 hrs

Presentations and panel discussion on medical cannabis:

Rosalie Pacula, Ph.D., RAND Drug Policy Research Center
Almut Winterstein, Ph.D., University of Florida, College of Pharmacology
Andrew Freedman, former Director of Marijuana Coordination in Colorado
Chief Daniel Oates, Florida Police Chiefs Association
Sheriff Bob Gualtieri, Florida Sheriffs Association
Lt. Colonel Mike Thomas, Department of Highway Safety & Motor Vehicles

NOTICE FINALIZED on 01/18/2017 4:01PM by Iseminger.Bobbye

Rosalie Pacula

Rosalie Liccardo Pacula is a senior economist at the RAND Corporation and a professor at the Pardee RAND Graduate School. She serves as director of RAND's BING Center for Health Economics, co-director of the RAND Drug Policy Research Center, and associate director of the data core for RAND's new U19 AHRQ-funded Health Care Delivery Systems Center. Her research at RAND over the last 20 years has largely focused on issues related to illegal or imperfect markets (health care markets, insurance markets, illicit drug markets), measurement of the size of these markets, the impact they have on behavior (suppliers and consumers), and the effectiveness of policy interventions at targeting behavior within these markets. Currently, her funded projects include an evaluation of the impact of medical marijuana policies on the consumption of and public health harms associated with recreational marijuana, an examination of barriers to the diffusion of buprenorphine (an evidence-based pharmacotherapy for heroin addiction), an examination of the impacts of formulary management and benefit design strategies on prescription opioid misuse, an exploration of factors defining high performing health care systems, and the construction of an international microsimulation platform that can be used to evaluate the effectiveness and cost-effectiveness of alternative alcohol prevention and treatment strategies. Pacula has been a member of the National Bureau of Economic Research (NBER) since 1997, serves on the editorial board of several journals, and is a scientific reviewer for the National Institutes of Health's HSOD committee. She received her Ph.D. in economics from Duke University.

Regulating Medical Marijuana Markets

Insights from Scientific Evaluations of State Experiments

Rosalie Liccardo Pacula

CT-461

Testimony presented before the Florida House of Representatives Health & Human Services Committee, Subcommittee on Health Quality on January 25, 2017.



For more information on this publication, visit www.rand.org/pubs/testimonies/CT461.html

Testimonies

RAND testimonies record testimony presented or submitted by RAND associates to federal, state, or local legislative committees; government-appointed commissions and panels; and private review and oversight bodies.

Published by the RAND Corporation, Santa Monica, Calif.

© Copyright 2017 RAND Corporation

RAND® is a registered trademark.

Limited Print and Electronic Distribution Rights

This document and trademark(s) contained herein are protected by law. This representation of RAND intellectual property is provided for noncommercial use only. Unauthorized posting of this publication online is prohibited. Permission is given to duplicate this document for personal use only, as long as it is unaltered and complete. Permission is required from RAND to reproduce, or reuse in another form, any of its research documents for commercial use. For information on reprint and linking permissions, please visit www.rand.org/pubs/permissions.html.

Regulating Medical Marijuana Markets

Insights from Scientific Evaluations of State Experiments

Testimony of Rosalie Liccardo Pacula¹
The RAND Corporation²

Before the Committee on Health & Human Services
Subcommittee on Health Quality
Florida House of Representatives

January 25, 2017

Chairman Pigman, Vice Chairman Plasencia, and other distinguished members of the Health Quality Subcommittee, thank you very much for the opportunity to testify before you today. I am a senior economist at the RAND Corporation, where I also serve as the co-director of the RAND Drug Policy Research Center.

For the past six years, I have been the principal investigator on a National Institute on Drug Abuse-sponsored grant, conducting research on the public health impacts of medical marijuana laws. During this time, I developed a marijuana policy tracking data system that helped identify various attributes of medical marijuana laws that are important for influencing behavior of both patients and recreational users. In addition, I have evaluated impacts of medical marijuana laws and the implementation of marijuana legalization in the state of Washington and co-authored work with my RAND colleagues on legalization options for the state of Vermont. It is my experience with evaluation of marijuana laws and policies that I draw on in my remarks to you today.

Under Amendment 2, the Florida legislature must develop and pass legislation implementing the changes required by the constitutional amendment. Medical marijuana programs across states vary widely, and the legislature will want to consider how to structure Florida's expanded program so as to meet the intensions of the voters. I will focus my remarks today on three specific issues.

¹ The opinions and conclusions expressed in this testimony are the author's alone and should not be interpreted as representing those of the RAND Corporation or any of the sponsors of its research.

² The RAND Corporation is a research organization that develops solutions to public policy challenges to help make communities throughout the world safer and more secure, healthier and more prosperous. RAND is nonprofit, nonpartisan, and committed to the public interest.

1. The variety of different supply structures that might be used to provide medical marijuana. The structure of medical marijuana supply can greatly influence the size of the market that results and states have experimented with a variety of approaches.
2. The impact of commercialization of medical marijuana. Commercialization occurred in states that had adopted relatively lax regulations (e.g., on the number of outlets and amount that could be sold) prior to the federal government's shift in enforcement in 2009.
3. The impact of medical marijuana laws on youth. While most of the scientific literature finds no impact of simply passing these laws on youth use, recent studies that account for rapid growth in these markets suggest youth use and outcomes may have been impacted.

I will address each of these in order.

Supply Structures for Medical Marijuana

Inquiries about the regulatory structure for supplying medical marijuana usually begin with a discussion of licensing and permissions given to entities that are responsible for cultivating, processing, distributing, and selling marijuana for medicinal purposes. In Florida, these entities will be the Medical Marijuana Treatment Centers (MMTCs). I found nothing in the statutory language that predetermines how this supply structure must be or how licenses and permissions must be set up, which means that the government has the flexibility to consider a variety of options. Let me offer some insights from two alternative approaches.

First, Florida might want to adopt regulations previously implemented in other medical marijuana states. With my colleagues at Beasley School of Law at Temple University, I examined how marijuana was supplied within states that had passed medical marijuana legislation as of July 1, 2016.³ We found substantial variability existed in these 24 states and the District of Columbia in how marijuana was supplied for medicinal purposes. Most states (21 out of 25) legally regulated dispensaries, and all but one of those states (Maryland) regulated the supply sources of marijuana sold through dispensaries.⁴ States differed in who they allowed to supply marijuana to the dispensaries. Some states (13 out of 20) allowed dispensaries to grow and sell their own product (either on site or at another location), housing the entire supply chain within a single business. Eight states allowed dispensaries to sell their excess supply to other dispensaries. In eight states, licensed cultivators/producers were the named source of suppliers to dispensaries. In other states, regulators tried to restrict the size of dispensaries or create a supply structure similar to a communal gardens or co-op. Patients (in four states) or caregivers (in five states) could grow their own marijuana and provide it to the dispensary; those same patients and caregivers were eligible to purchase from the dispensary as well.

³ While the paper summarizing our analyses of these laws is still under review, the data we used to generate the summary is publicly available on the Prescription Drug Abuse Policy System webpage (www.pdaps.org).

⁴ Those states that did not regulate or legally permit dispensaries as of July 2016 include Alaska, Michigan, Montana, and Pennsylvania. The first three states all allow patient cultivation, while Pennsylvania's law was only passed in April 2016, so the specific provisions regarding access had not been developed yet. Legally allowing dispensaries and tolerating them are two different things, of course.

Other elements of dispensary regulation that have been adopted include limits on store density (14 states); a cap on the total number of dispensaries allowed throughout the state (14 states); restrictions on dispensary locations (18 states); allowances for local zoning rules to apply (16 states); and limits on the stock amount of marijuana that can be maintained at the site (11 states). States with stock limits use a variety of approaches, including usable marijuana (seven states), number of mature plants (five states), number of immature plants (four states), and/or number of plants regardless of maturity (two states). Ten states do not set limits on dispensary stock amounts (which would influence the amount of marijuana available in the market at one point in time).

Much attention has been given to structural requirements for dispensaries, such as security systems (20 states) and secure spaces accessible only to cardholders and/or authorized dispensary employees (19 states) to ensure children or unauthorized persons do not access marijuana. Similarly, many states have adopted product safety regulations (20 states), such as testing requirements, labeling requirements (21 states), and packaging requirements and/or restrictions (18 states). Regulations in this last area continue to evolve and remain fairly naive, as new problems arising from testing of edibles, testing in general, and the use of pesticides continue to emerge in both medical and recreational markets.⁵

A second approach that this committee might take in considering supply structures for medical marijuana in the state of Florida is to “think outside of the box” and consider market structures that have not yet been tried in existing medical or recreational markets. In a recent RAND report to the secretary of administration for Vermont, we identified ten alternative models of supply for marijuana in lieu of prohibition.⁶ While the for-profit commercial system of Colorado, California, and Washington is one of those options, several “middle-ground” options also exist that could feasibly meet voters’ intentions of increasing access for patients while also precluding the development of a for-profit commercial market. Some of these options include the creation of a public authority or the granting of licenses to businesses that serve other objectives rather than profit maximization, such as “for-benefit corporations.”

Today, all medical marijuana states have chosen the licensing of either for-profit or nonprofit entities to supply and sell marijuana, although many add additional controls on the size of the market, such as limiting the number of entities allowed to receive licenses or the number of total outlets. These additional controls reflect the experience in California, where simply restricting the market to nonprofits has not prevented the market from becoming competitive or commercialized. Several states, such as Connecticut, New Jersey, and New York, seriously

⁵ Jonathan P. Caulkins, Beau Kilmer, Mark Kleiman, Robert J. MacCoun, Gregory Midgette, Pat Oglesby, Rosalie Liccardo Pacula, and Peter H. Reuter, *Considering Marijuana Legalization Insights for Vermont and Other Jurisdictions*, Santa Monica, Calif.: RAND Corporation, RR-864, 2015; T.S. Ghosh, M. Van Dyke, A. Maffey, E. Whitley, D. Erpelding, and L. Wolk, “Medical Marijuana’s Public Health Lessons—Implications for Retail Marijuana in Colorado,” *New England Journal of Medicine*, Vol. 372, No. 11, 2015, pp. 991–993; and D. Stone, “Cannabis, Pesticides and Conflicting Laws: The Dilemma for Legalized States and Implications for Public Health,” *Regulatory Toxicology and Pharmacology*, Vol. 69, No. 3, 2014, pp. 284–288.

⁶ Caulkins et al., 2015.

restrict the number of licenses given out and number of outlets allowed. Other states, like Colorado, California, and Washington, have let the market decide for itself.

It is worth noting that the state of Washington has taken a different approach in its development of a legal recreational market than its medicinal market, requiring separate licenses for cultivators, manufacturers or processors, and retailers, as well as licensing or certification for testing facilities (which also is true of Colorado, Oregon, and Alaska). Washington is the only nonmedical legalizing state to date that restricts the number of licenses a single firm can own and prohibits license holders from being involved in both production and retail. Washington has further limited the number of retail store licenses available in an attempt to avoid issues related to overproduction, although the number of licenses has expanded over time. Other recreational marijuana states have not created such restrictions on the number of retail outlets. All legalizing states, except Alaska, restrict the size of cultivation facilities, and Washington has an additional cap on total statewide production. These differences in the structure of the market should theoretically influence the availability and cost of marijuana in each state, and Washington is now forcing some of these same restrictions on its medical market.

The Impact of Commercialization

Two primary concerns exist regarding commercialization of the medical marijuana industry. First, commercialization is expected to substantially reduce production costs, and hence the price of medical marijuana, as competition causes firms to innovate and find ways to reduce their costs and extract higher profits.⁷ Second, commercialization generates financial incentives for legal suppliers to promote their product to heavy consumers who, just like in any other market, represent the vast majority of the total amount sold and/or consumed.⁸ While lower costs for medical products are certainly not a bad thing, recent evidence suggests that the vast majority of medical users also use marijuana recreationally.⁹ This reinforces concerns that not all medical marijuana is being purchased for medicinal purposes.

Scientific evidence of the commercialization of medical markets comes largely from evidence in states that were early adopters of medical marijuana laws (e.g., California, Colorado, and Washington). In the 1990s, when these states initially passed ballot initiatives to allow for medical marijuana, they purposefully set up weak state regulations of their supply chains because

⁷ J.P. Caulkins, A. Hawken, B. Kilmer, and M. Kleiman, *Marijuana Legalization: What Everyone Needs to Know*. New York: Oxford University Press, 2012; and J.P. Caulkins and B. Kilmer, "Considering Marijuana Legalization Carefully: Insights for Other Jurisdictions from Analysis for Vermont," *Addiction*, Vol. 111, 2016, pp. 2082–2089.

⁸ Caulkins and Kilmer, 2016; and T. Subritzky, S. Pettigrew, and S. Lenton, "Issues in the Implementation and Evolution of the Commercial Recreational Cannabis Market in Colorado," *International Journal of Drug Policy*, Vol. 27, 2016, pp. 1–12.

⁹ R.L. Pacula, M. Jacobson, and E.J. Maksabedian, "In the Weeds: A Baseline View of Cannabis Use Among Legalizing States and Their Neighbors," *Addiction*, Vol. 111, 2016, pp. 973–980; G.L. Schauer, B.A. King, R.E. Bunnell, G. Promoff, and T.A. McAfee, "Toking, Vaping, and Eating for Health or Fun: Marijuana Use Patterns in Adults, U.S., 2014," *American Journal of Preventive Medicine*, Vol. 50, No. 1, 2016, pp. 1–8.

of the considerable uncertainty regarding a federal response to any formal state regulation.¹⁰ Initially, the federal government enforced the national prohibition in markets in some of these states. However, in 2009, two federal actions led to a perceived change in the federal position regarding enforcement of the federal prohibition of marijuana. First, in March 2009, Attorney General Eric H. Holder, Jr. announced an end to raids on distributors of medical marijuana in states where medical marijuana was legal.¹¹ Then, in October of the same year, the Justice Department issued a memo to all federal prosecutors that deprioritized the federal prosecution of medical marijuana users and suppliers who were in “clear and unambiguous compliance with existing state law.”¹² This “pass” from the federal government allowed medical markets in weakly regulated states to proliferate.¹³

Evidence of rapid commercialization in response to federal leniency is most evident in Colorado, which experienced two other important state policy revisions in 2009 that further enabled the development of dispensaries and large medical marijuana centers.¹⁴ The number of individuals who registered to become a patient in Colorado in 2009 skyrocketed. At the beginning of the year (January 2009), the Colorado Department of Public Health and Environment had received only 6,369 total patient applications since medical marijuana was legalized in 2000. By the end of 2009, 41,039 new patients had registered, and this number grew to over 115,000 in 2010.¹⁵ Newspapers and law enforcement reported similar rises in the number of dispensaries during these two years, although official numbers were not yet being collected.

Only a few published studies have closely analyzed the impacts of this rapid growth in the medical marijuana market during the 2009 period.¹⁶ In general, these studies find consistent evidence that perceived harmfulness of marijuana declined with the commercialization of marijuana, and several indicators of problematic use increased, as indicated by fatal crashes

¹⁰ R.L. Pacula and R. Smart, “Effects of Changes in Marijuana Laws on Marijuana Use and Disorders: Medical Marijuana and Marijuana Legalization,” *Annual Review of Clinical Psychology*, Vol. 13, No. 1, 2017.

¹¹ D. Johnston and N.A. Lewis, “Obama Administration to Stop Raids on Medical Marijuana Dispensers,” *New York Times*, March 18, 2009.

¹² D.W. Ogden, *Investigations And Prosecutions in States Authorizing the Medical Use of Marijuana. Memorandum For Selected United States Attorneys*, Washington, D.C.: U.S. Department of Justice, Office of the Deputy Attorney, 2009.

¹³ C. Cambron, K. Guttmanova, and C.B. Fleming, “State and National Contexts in Evaluating Cannabis Laws: A Case Study of Washington State,” *Journal of Drug Issues*, Vol. 47, No. 1, 2017, pp. 74–90; and R. Smart, *Essays on the Effects of Medical Marijuana Laws*, Los Angeles, University of California, 2016.

¹⁴ J.M. Davis, B. Mendelson, J.J. Berkes, K. Suleta, K.F. Corsi, and R.E. Booth, “Public Health Effects of Medical Marijuana Legalization in Colorado,” *American Journal of Preventive Medicine*, Vol. 50, No. 3, 2016, pp. 373–379; and S. Salomonsen-Sautel, S.J. Min, J.T. Sakai, C. Thurstone, and C. Hopfer, “Trends in Fatal Motor Vehicle Crashes Before and After Marijuana Commercialization in Colorado,” *Drug and Alcohol Dependence*, Vol. 140, 2014, pp. 137–144.

¹⁵ Smart, 2016; Ghosh et al., 2016.

¹⁶ Cambron, Guttmanova, and Fleming, 2017; Davis et al., 2016; Salomonsen-Sautel, et al., 2014; J. Schuermeyer, S. Salomonsen-Sautel, R.K. Price, S. Balan, C. Thurstone, S. Min, and J. Sakai, “Temporal Trends in Marijuana Attitudes, Availability and Use in Colorado Compared to Non-Medical Marijuana States: 2003–2011,” *Drug and Alcohol Dependence*, Vol. 140, 2014, pp. 145–155; and Smart, 2016.

involving marijuana, poison calls involving marijuana, and dependent use among youth.¹⁷ Some of these findings stand in stark contrast to evidence that evaluates the impact of passing a medical marijuana law, which shows a reduction in fatal crashes with the passage of these laws.¹⁸ The difference in findings stems from the difference in evaluating the medical marijuana market from legalization on versus evaluating the effects of the medical marijuana market when it grows substantially in size.

Additional insights on the effects of commercialization come from analyses of the density of marijuana outlets on marijuana use and health harms (and I emphasize health harms because virtually no work has been done evaluating the effects of commercialization on health benefits, with the exception of opioid mortality). In a series of papers examining outlet density across 50 cities in the state of California, Dr. Bridget Freisthler and colleagues examined the relationship between greater marijuana outlet density and a variety of measures, including frequency of marijuana use in the past year and hospitalizations for marijuana dependence.¹⁹ In both of these instances, she found a positive association between outlet density and the outcome of interest—as density increased, so did frequency of use and hospitalizations. She did not, however, find any relationship between outlet density and crime.²⁰

One final consideration related to the effects of commercialized markets pertains to the role of advertising in these markets. My colleagues at the RAND Corporation conducted a study of more than 8,200 students from 16 middle schools in southern California in 2010 and 2011, when the promotion of medical marijuana was accelerated in California.²¹ They found that over time, a growing number of middle school students reported seeing at least one medical marijuana advertisement on a billboard, in a magazine, or in other locations in the past three months (rising from 22 percent in 2010 to 30 percent in 2011). Similar to alcohol, they found that greater exposure to medical marijuana advertisements at an early age (age 13) was associated with greater intentions to use marijuana and higher actual marijuana use one year later.²² Given the very strong association between early initiation of marijuana and later dependence, they

¹⁷ Davis et al., 2016; Salomonsen-Sautel et al., 2014; Schuermeyer et al., 2014; and Smart, 2016.

¹⁸ D.M. Anderson, B. Hansen, and D.I. Rees, “Medical Marijuana Laws, Traffic Fatalities, and Alcohol Consumption,” *Journal of Law & Economics*, Vol. 56, 2013, pp. 333–369; and J.Santaella-Tenorio, C.M. Mauro, M.M. Wall, J.H. Kim, M. Cerdá, K.M. Keyes, D.S. Hasin, S. Galea, and S.S. Martins, “US Traffic Fatalities, 1985–2014, and Their Relationship to Medical Marijuana Laws,” *American Journal of Public Health*, Vol. 107, No. 2, 2017, pp. 336–342.

¹⁹ B. Freisthler and P.J. Gruenewald, “Examining The Relationship Between the Physical Availability of Medical Marijuana and Marijuana Use Across Fifty California Cities,” *Drug and Alcohol Dependence*, Vol. 143, 2014, pp. 244–250; and C. Mair, B. Freisthler, W.R. Ponicki, and A. Gaidus, “The Impacts of Marijuana Dispensary Density and Neighborhood Ecology on Marijuana Abuse and Dependence,” *Drug and Alcohol Dependence*, Vol. 154, 2015, pp. 111–116.

²⁰ N. J. Kepple and B. Freisthler, “Exploring the Ecological Association Between Crime and Medical Marijuana Dispensaries,” *Journal of Studies on Alcohol and Drugs*, Vol. 73, No. 4, 2012, pp. 523–530.

²¹ E.J. D’Amico, J.N. Miles, and J.S. Tucker, “Gateway to Curiosity: Medical Marijuana Ads and Intention and Use During Middle School,” *Psychology of Addictive Behaviors*, Vol. 29, No. 3, 2015, p. 613.

²² D’Amico, Miles, and Tucker, 2015.

recommended that regulators consider advertising restrictions similar to those of alcohol and tobacco products—even for medical marijuana.

The Impact of Medical Marijuana Laws on Youth

While this is a question that has received considerable attention in the academic literature and while I acknowledge that the bulk of the existing research shows no statistical association between medical marijuana laws and youth marijuana prevalence, I believe the question remains far from answered for two reasons.²³ First, the majority of published studies evaluating the impacts of medical marijuana laws on use by youth treat medical marijuana laws as if they can be placed into two simple buckets; for example, states can be meaningfully separated into those that have a medical marijuana law and those that do not or into those that have dispensaries and those that do not. Using such simple characterizations of these laws leads analysts to treat states like New York and Connecticut similarly to states like Colorado and California because they all have medical marijuana laws and they all legally protect dispensaries. Anyone familiar with these specific state markets knows, however, that their policies are in fact quite different.

Recently, researchers have begun developing new ways of measuring the size of these medical markets, rather than their simple existence, to better understand their impacts on youth use and other outcomes.²⁴ Work by Rosanna Smart (2016), for example, shows that a one percentage point increase in the share of adults registered as medical marijuana patients within the state increases the prevalence of past month marijuana use among youth by 5–6 percent, while also increasing traffic fatalities by 7 percent and alcohol poisoning deaths by 4 percent. Her results are consistent with evidence from Colorado evaluating the impact of the commercialization of marijuana on youth use, which I discussed previously.²⁵ The fact that this alternative characterization of markets generates different findings from the previous literature leaves me questioning the robustness of the conclusion that medical marijuana laws do not impact marijuana use among youth.

The second reason why I am not convinced by the current evidence that there is no relationship between medical marijuana laws and youth use is the consistent evidence from studies showing that these laws influence perceptions of harm among most adolescents, with the

²³ D.M. Anderson, B. Hansen, and D.I. Rees, “Medical Marijuana Laws and Teen Marijuana Use,” *American Law and Economics Review*, Vol. 17, No. 2, 2015, pp. 495–528; D.S. Hasin, M. Wall, K.M. Keyes, M. Cerdá, J. Schulenberg, P.M. O’Malley, S. Galea, R. Pacula, and T. Feng, “Medical Marijuana Laws and Adolescent Marijuana Use in the USA from 1991–2014: Results From Annual, Repeated Cross-Sectional Surveys,” *Lancet Psychiatry*, Vol. 2, No. 7, 2015, pp. 601–608; E.K. Choo, M. Benz, N. Zaller, O. Warren, K.L. Rising, K.J. McConnell, “The Impact of State Medical Marijuana Legislation on Adolescent Marijuana Use,” *Journal of Adolescent Health*, Vol. 55, No. 2, 2014, pp.160–166; and S.D. Lynne-Landsman, M.D. Livingston, and A.C. Wagenaar, “Effects of State Medical Marijuana Laws on Adolescent Marijuana Use,” *American Journal of Public Health*, Vol. 103, No. 8, 2013, pp. 1500–1506.

²⁴ Cambron, Guttmanova, and Fleming, 2017; Davis et al., 2016; Smart, 2016.

²⁵ Davis et al., 2016; Schuermeyer et al., 2014; Salomonsen-Sautel et al., 2014.

possible exception of the very young.²⁶ If these laws are effective at reducing perceptions of harm, then evidence by Lloyd Johnston and his “Monitoring the Future” colleagues clearly suggests that we can expect consumption to increase over time.²⁷ Few analyses have considered the lagged effects changes in perceptions might eventually have on youth use.

There is one area where there is clear evidence of a harmful impact of these laws on youth, and that is the problem of toxic ingestions of edibles by children.²⁸ Due to concerns regarding accidental ingestion of edibles by children, even states with recreational laws continue to adopt and evolve their regulations specific to marijuana-infused products. New regulations continue to evolve pertaining to stricter packaging and labeling requirements, potency limits on individual serving sizes, and processing method requirements. The actual effectiveness of these policies is currently unknown, as edibles can be made at home with a number of other marijuana products. Thus, it remains unclear to what extent regulation focused on edibles will reduce the harm that comes from accidental ingestion.

In closing, I’d like to stress that while various medical marijuana experiments have indeed taken place in the United States, each experience has been unique. States have chosen different avenues regarding the degree to which they are willing to regulate these markets, the suppliers, products, and consumers. The changing federal position regarding enforcement of the prohibition has also influenced these markets and complicated evaluations of their effects. While a lot of literature has been emerging on the impacts of medical marijuana, this remains a scientific area where policy is very much in motion and few lessons can be drawn with much certainty.

²⁶ C.B. Fleming, K. Guttmannova, C. Cambron, I.C. Rhew, and S. Oesterle, “Examination of the Divergence in Trends for Adolescent Marijuana Use and Marijuana-Specific Risk Factors in Washington State,” *Journal of Adolescent Health*, Vol. 59, No. 3, 2016, pp. 269–275; S. Khatapoush and D. Hallfors, “‘Sending the Wrong Message’: Did Medical Marijuana Legalization in California Change Attitudes About and Use of Marijuana?” *Journal of Drug Issues*, Vol. 34, No. 4, 2004, pp. 751–770; K.M. Keyes, M. Wall, M. Cerdá, J. Schulenberg, P.M. O’Malley, S. Galea, T. Feng, and D.S. Hasin, “How Does State Marijuana Policy Affect US Youth? Medical Marijuana Laws, Marijuana Use and Perceived Harmfulness: 1991–2014,” *Addiction*, Vol. 111, No. 12, 2016, pp. 2187–2195; and Schuermeyer et al., 2014.

²⁷ J.G. Bachman, L.D. Johnston, and P.M. O’Malley, “Smoking, Drinking, and Drug Use Among American High School Seniors: Correlates and Trends, 1975–1979,” *American Journal of Public Health*, Vol. 71, No. 1, 1981, pp. 59–69; J.G. Bachman, L.D. Johnston, and P.M. O’Malley, “Explaining Recent Increases in Students’ Marijuana Use: Impacts of Perceived Risks and Disapproval, 1976 Through 1996,” *American Journal of Public Health*, Vol. 88, No. 6, 1998, pp. 887–892; and R.L. Pacula, M. Grossman, F.J. Chaloupka, P. O’Malley, L.D. Johnston, and M.C. Farrelly, “Marijuana and Youth,” in Jonathan Gruber, ed. *Risky Behavior Among Youths: An Economic Analysis*. Chicago, Ill.: University of Chicago Press, 2001, pp. 193–191.

²⁸ G.S. Wang, G. Roosevelt, and K. Heard, “Pediatric Marijuana Exposures in a Medical Marijuana State,” *JAMA Pediatrics*, Vol. 167, 2013, pp. 630–633; and G.S. Wang, G. Roosevelt, M.C. Le Lait, E.M. Martinez, B. Bucher-Bartelson, A.C. Bronstein, and K. Heard, “Association of Unintentional Pediatric Exposures with Decriminalization of Marijuana in the United States,” *Annals of Emergency Medicine*, Vol. 63, 2014, pp. 684–689.

Almut Winterstein

Almut Winterstein received her pharmacy degree from Friedrich Wilhelm University in Bonn, Germany and her Ph.D. in Pharmacoepidemiology from the Humboldt University in Berlin, Germany. She joined faculty at the University of Florida in 2000 and holds the position of Professor in the Department of Pharmaceutical Outcomes and Policy at the College of Pharmacy, and in the Department of Epidemiology at the Colleges of Public Health and Health Professions and Medicine.

Almut's research interests focus on drug safety and effectiveness, and the evaluation and prevention of inappropriate medication use. Clinical focus areas of pharmacoepidemiologic studies include pediatrics, psychiatry, infectious disease, and diabetes mellitus. Her interest in quality-of-care issues focuses on the development and evaluation of medication safety programs, clinical decision support systems and quality metrics. Almut has received funding from CMS, FDA, AHRQ, and various professional associations and state agencies including the Florida Department of Health.

She currently chairs the FDA/CDER Drug Safety and Risk Management Advisory Board (DSaRM), is a member of the Federal Interagency Work Group on Adverse Drug Events, and is consultant on medication safety issues for the Florida Department of Rural Health



Medical Marijuana Surveillance System and Research Infrastructure

Health Quality Subcommittee, Florida House of Representatives
January 25th, 2017

Almut G Winterstein, RPh, PhD, FISPE

Professor & Chair Pharmaceutical Outcomes & Policy



Compassionate Medical Cannabis Act, Section 381.986(2)(e), Florida Statutes

- [Ordering physician must maintain] ... a patient treatment plan that includes the dose, route of administration, planned duration, and monitoring of the patient's symptoms and other indicators of tolerance or reaction to the low-THC cannabis or medical cannabis;
- Submits the patient treatment plan quarterly to the University of Florida College of Pharmacy for research on the safety and efficacy of low-THC cannabis and medical cannabis.

Status Quo to meet the mandate

- Developed “bare bones” online data entry form
- Meets state and federal standards for protection of personal health information
- One-sided communication only: providers submit encrypted form to UF with no ability to
 - See submitted information
 - Auto-populate information submitted previously
 - Tailor data collection to entered information (interactive data entry form)
- No linkage to Compassionate Use Registry
- No review or analysis of submitted information



Initial Treatment Plan

*Date of treatment plan submission:

Patient Information

*Registry ID Number:

*Patient Zip Code:

*Patient DOB:

*Patient Race/Ethnicity:

Provider Information

*Full Name:

*Address:

*NPI #:

*DEA #:

*Medical License:

*Facility Name:

*Phone:

Fax:

*Specialty/Board certifications:

Cannabis Order

Date of Order:

Dose:

Type: Low-THC Cannabis Medical Cannabis

Planned duration:

Clinical History and Condition

Indication(s) for cannabis treatment

Chief complaint for evaluation of cannabis treatment:

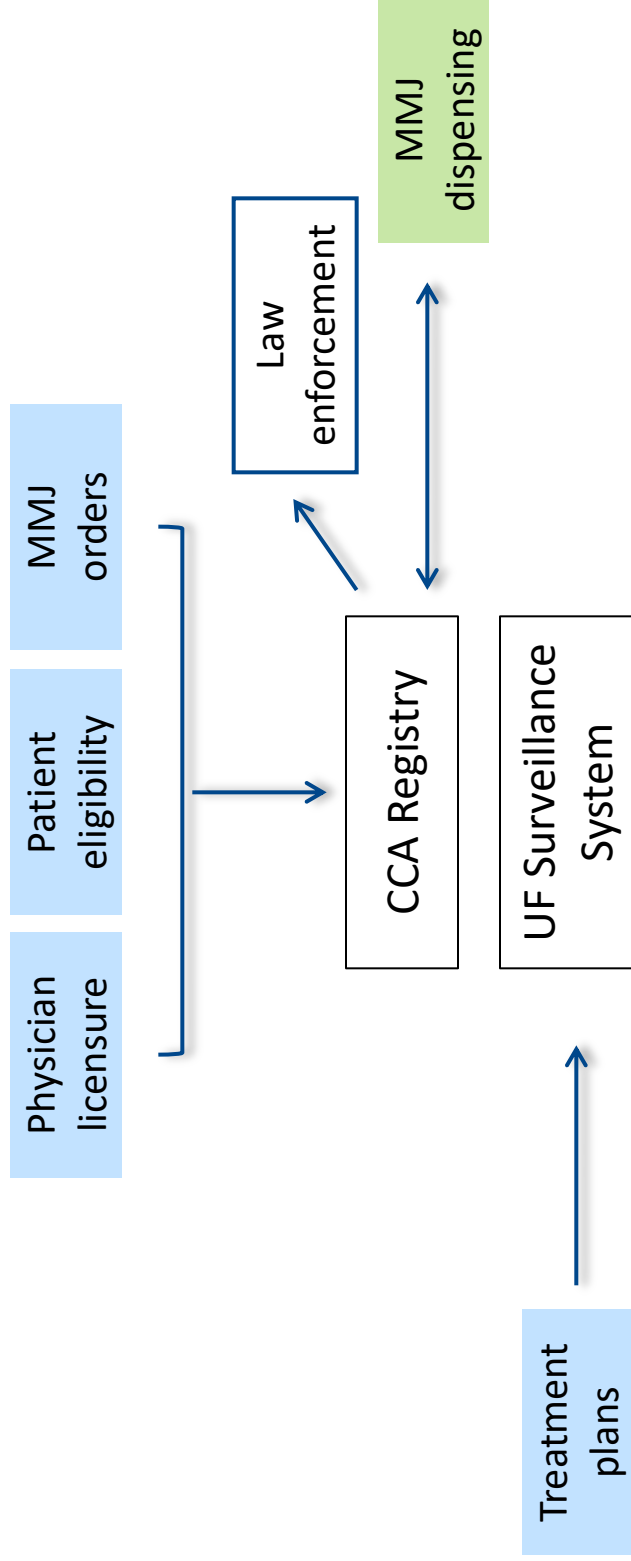
Experience

- Daily inquiries by providers & patients
 - General information about enrolment
 - Clarification or amendments to submitted information
 - Complaints about cumbersome data entry
 - Utilization pattern
 - Information on safety and efficacy (from both patients and providers)
- Increasing rate of new patients but lagging behind enrolment in registry
 - 600 unique patients in UF system versus 2000 in registry

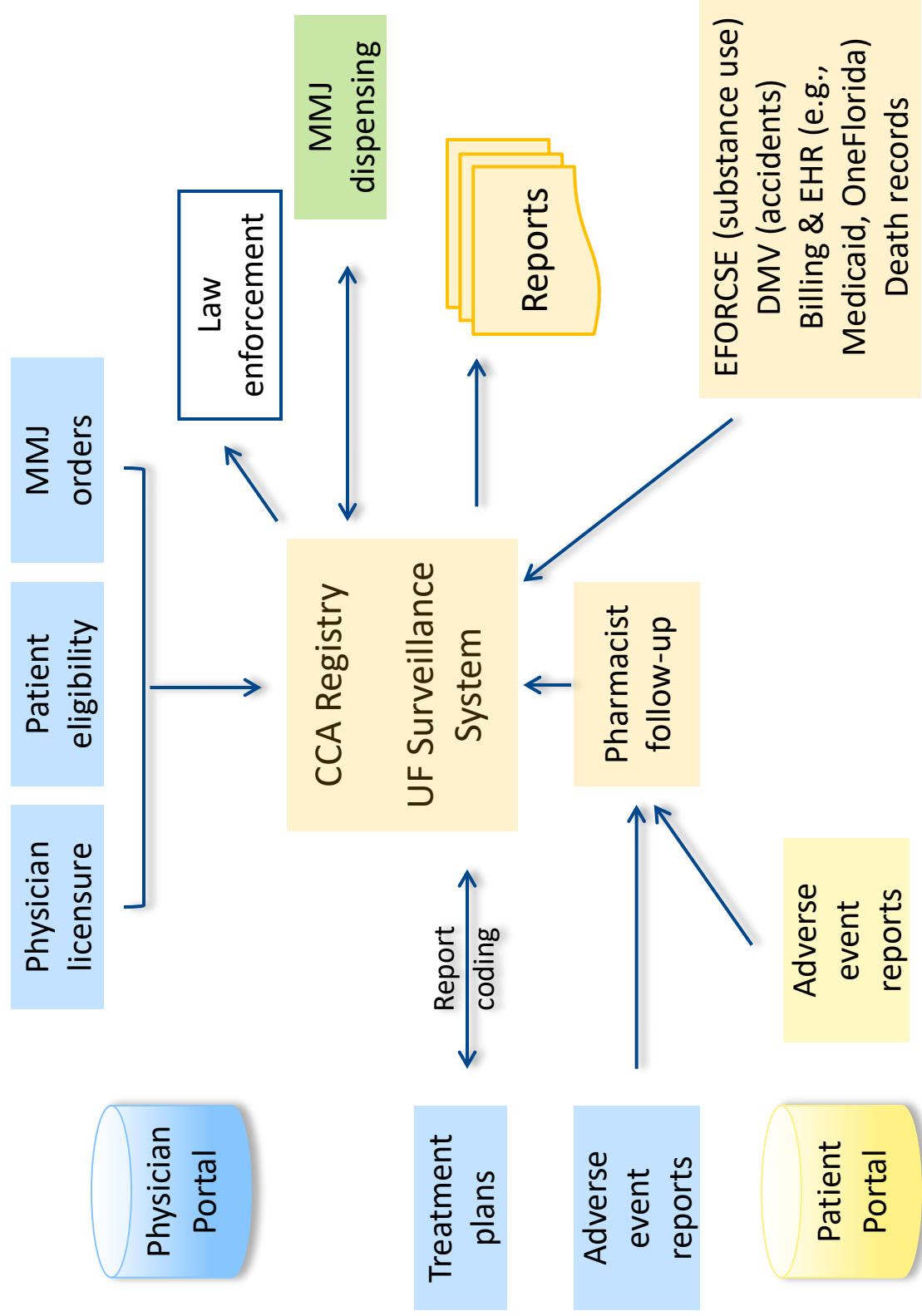
Motivation for Design of UF Integrated Surveillance System Proposal

- Evidence for MMJ safety and effectiveness is lacking: risk-benefit is unclear
- Medical treatment is made available without safety net (as defined in FDCA for drugs)
 - Stringent efficacy and safety testing prior to approval
 - Passive and – as needed – active surveillance or formal safety studies post-approval
- No capability to
 - Identify emerging safety signals
 - Flag patients at higher risk for adverse events
 - Evaluate effectiveness

Current Surveillance System

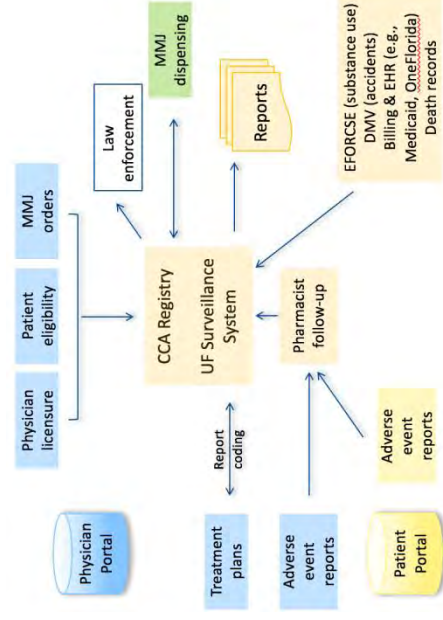


Integrated Surveillance System



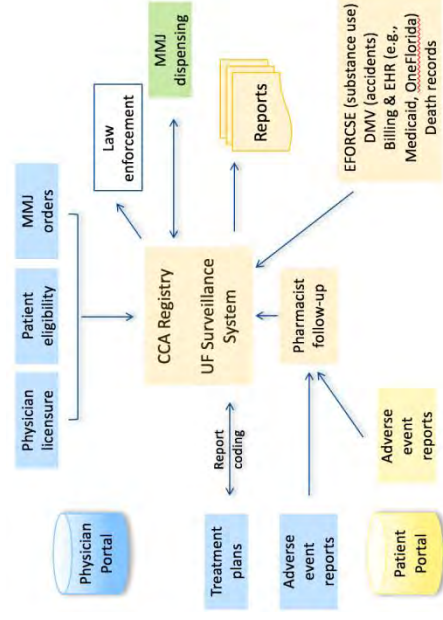
Capabilities of Surveillance System: Enhanced data flow

- Physician 2-way interaction with UF system
Allows auto-populated fields, review of submitted information, tailored treatment plan forms.
- Linkage of registry and UF system
Allows monitoring of physician compliance with treatment plan submission.



Capabilities of Surveillance System: Treatment plan analyses

- Treatment plan coding and data cleaning
 - Allows analysis of patient and provider demographics and patient clinical information
- Biannual reports on utilization including
 - identification of high utilizers
- Summary of clinical information in treatment plans



Capabilities of Surveillance System: active adverse event surveillance and controlled outcomes studies

- Systematic ascertainment of adverse events similar to FDA passive surveillance system for drugs
 - Rapid capture of emerging safety signals
- Safety studies via data linkage
 - Hospitalizations / deaths
 - Traffic accidents
 - Co-medication with psychogenic properties and other drug-drug interactions or contraindications (vulnerable populations)
- Effectiveness studies via data linkage
 - Allows control groups and comprehensive outcomes ascertainment



Almut G. Winterstein, RPh, PhD, FISPE
Professor & Chair
Pharmaceutical Outcomes & Policy
University of Florida

almut@ufl.edu

Andrew Freedman

Andrew Freedman holds a bachelor's degree in philosophy and political science from Tufts University and, in 2010, earned his J.D. from Harvard Law School. Upon law school graduation, Andrew joined John Hickenlooper's campaign for governor – and was tapped to serve as Lt. Gov. Joe Garcia's Chief of Staff. During his time with Garcia, the lieutenant governor's office won a \$45 million Race to the Top Grant for early childhood education, created the Office of Early Childhood, helped pass the READ act, and collaborated with Mile High United Way to create the Colorado Reading Corps. In 2013, Andrew left the lieutenant governor's office to become the Director of Colorado Commits to Kids, the Yes on 66 campaign – the largest effort to date to overhaul Colorado's education funding system. In 2014, Andrew was appointed the state's first Director of Marijuana Coordination and served in this capacity until January 5, 2017. As Director, Andrew's mission was to ensure the efficient and effective regulation of Colorado's retail and medical marijuana while promoting public health, maintaining public safety, and keeping marijuana out of the hands of children.

Chief Daniel Oates

Chief Daniel J. Oates

Daniel J. Oates was appointed as the 19th Chief of the Miami Beach Police Department on June 9, 2014. The City of Miami Beach employs 407 police officers and 116 civilians and operates with a budget of approximately \$104 million. The MBPD serves a resident population of 91,000, with an average daily population of 250,000. It is one of nation's leading tourist destinations, hosting 280 days a year of special events that attract over 9 million local, national and international visitors.

Prior to his appointment in Miami Beach, Chief Oates served for nearly nine years as the Chief of Police for the City of Aurora, Colorado, a major suburb Denver with a population of 350,000. During his time in Aurora, he oversaw a 30-percent reduction in major index crime in Aurora. Prior to his appointment in Aurora, Chief Oates served for four years as Chief of Police and Safety Services Administrator for the City of Ann Arbor, Michigan, where he was responsible for all police, fire and emergency management services for a city of 114,000 that included the University of Michigan. During his time in Ann Arbor, he oversaw a 24-percent reduction in major crime.

From 1980 through 2001, Chief Oates served in the New York Police Department. He finished his NYPD career as a Deputy Chief and the Executive Officer and second-in-command of the Patrol Borough Brooklyn South, where he supervised 3,000 patrol officers and 700 civilians and was responsible for all patrol services for 1.4 million residents in the City's largest borough. Between 1997 and 2001, Chief Oates served as the Commanding Officer of the NYPD's Intelligence Division. He was a member of the Police Commissioner's Executive Staff and served as his principal advisor on citywide security and intelligence matters. Chief Oates' prior NYPD assignments also included serving as the chief counsel and Commanding Officer of the Legal Bureau, the 85-attorney law office of the NYPD.

Chief Oates is a 1977 graduate of Bucknell University with a B.A. degree in English and a 1986 graduate of New York Law School. He is admitted to practice law in Colorado, New York and New Jersey. He also holds a 1993 Masters of Science Degree in Management from New York University. Chief Oates is also a member of numerous professional associations. He is a member of the Board of Directors of the Police Executive Research Forum (PERF), a long-time member of the International Association of Chiefs of Police (IACP), a Past President of the Colorado Association of Chiefs of Police and the past Vice-Chair of the Colorado Peace Officers Standards and Training (POST). Chief Oates also serves on the Criminal Intelligence Coordinating Council, the national advisory council of police chiefs and sheriffs, created in May, 2004 to advise the U.S. Attorney General and Secretary of Homeland Security on intelligence and security strategies in a post-9/11 world.



Florida Police Chiefs Association

Serving Florida's Law Enforcement Since 1952



CONSTITUTIONAL AMENDMENT No. 2

Article X, Section 29

The FPCA's recommendations regarding Amendment 2 and its impact on law enforcement are in **red**.

(Revised 1/23/17)

BALLOT TITLE: Use of Marijuana for Debilitating Medical Conditions

BALLOT SUMMARY: Allows medical use of marijuana for individuals with debilitating medical conditions as determined by a licensed Florida physician. Allows caregivers to assist patients' medical use of marijuana. The Department of Health shall register and regulate centers that produce and distribute marijuana for medical purposes and shall issue identification cards to patients and caregivers. Applies only to Florida law. Does not immunize violations of federal law or any non-medical use, possession or production of marijuana.

ARTICLE AND SECTION BEING CREATED OR AMENDED: Article X, Section 29

FULL TEXT OF THE PROPOSED CONSTITUTIONAL AMENDMENT:

ARTICLE X, SECTION 29. – Medical marijuana production, possession and use.

(a) PUBLIC POLICY.

(1) The medical use of marijuana by a qualifying patient or caregiver in compliance with this section is not subject to criminal or civil liability or sanctions under Florida law.

(2) A physician shall not be subject to criminal or civil liability or sanctions under Florida law solely for issuing a physician certification with reasonable care to a person diagnosed with a debilitating medical condition in compliance with this section.

The FPCA's Recommendation: The "reasonable care" language here provides ample leeway for either the Legislature or the Department of Health to establish very specific regulations for doctors who issue a "physician certification" to a medical marijuana user. Because this has been an area of very substantial abuse by some physicians in Colorado any finding by a physician that a patient meets the Amendment 2 criteria for medical marijuana should be based on thorough examination, a record of substantive treatment by the physician over an extended period of time, and ample documentation of the illness and the justification for marijuana as a viable treatment option. The Department of Health should fund and staff a robust inspection program to ensure compliance, with robust civil penalties for physicians who fail to comply.

(3) Actions and conduct by a Medical Marijuana Treatment Center registered with the Department, or its agents or employees, and in compliance with this section and Department regulations, shall not be subject to criminal or civil liability or sanctions under Florida law.

(b) DEFINITIONS. For purposes of this section, the following words and terms shall have the following meanings:

(1) "Debilitating Medical Condition" means cancer, epilepsy, glaucoma, positive status for human immunodeficiency virus (HIV), acquired immune deficiency syndrome (AIDS), post-traumatic stress disorder (PTSD), amyotrophic lateral sclerosis (ALS), Crohn's

disease, Parkinson's disease, multiple sclerosis, or other debilitating medical conditions of the same kind or class as or comparable to those enumerated, and for which a physician believes that the medical use of marijuana would likely outweigh the potential health risks for a patient.

(2) "Department" means the Department of Health or its successor agency.

(3) "Identification card" means a document issued by the Department that identifies a qualifying patient or a caregiver.

The FPCA's Recommendation: Any person who is a qualifying patient or caregiver, or involved in the ownership or operation of a Medical Marijuana Treatment Center (MMTC), including as an owner, investor, employee, distributor or transporter of medical marijuana, should be issued a state photo ID card similar to current ID cards and drivers licenses. Law enforcement must have unlimited 24-hour access to an accurate, up-to-date state registry to confirm that a person is a registered patient or caregiver, or an MMTC owner, investor, employee, distributor or transporter of medical marijuana.

With regard to any person who is an MMTC owner, investor, employee, distributor or transporter of medical marijuana, no such state photo ID card should be issued unless the applicant has undergone and passed a background check by an authorized agency. No person in this category who has been convicted of a state or federal felony or convicted of a misdemeanor drug offense within the past 10 years should be issued such a state photo ID card or permitted to be in possession of medical marijuana.

If a person is in legal possession of medical marijuana but not carrying his/her medical marijuana state photo ID card, he/she should be subject to a non-criminal violation resulting in a \$250.00 fine, payable to the clerk of the court, and revocation of the state photo ID card and the authority to possess medical marijuana if the fine is not paid.

(Note: The background investigation described here should be conducted by either a state or local law enforcement agency. The cost of the background investigation should be borne by the applicant and paid up front, before the investigation is begun and without regard to the findings of the investigation.)

The FPCA's Recommendation: In the interest of full disclosure and to ensure that organized crime does not infiltrate the medical marijuana industry, all owners and investors in MMTCs in Florida should undergo a thorough financial background investigation. The designated state department or agency should be staffed and funded to perform these background investigations properly and efficiently.

The FPCA's Recommendation: The state photo ID card for patients, caregivers and MMTC owners, investors, employees, distributors and transporters of medical marijuana should be applied for and reissued every year.

(4) "Marijuana" has the meaning given cannabis in Section 893.02(3), Florida Statutes (2014), and, in addition, "Low-THC cannabis" as defined in Section 381.986(1)(b), Florida Statutes (2014), shall also be included in the meaning of the term "marijuana."

(5) "Medical Marijuana Treatment Center" (MMTC) means an entity that acquires, cultivates, possesses, processes (including development of related products such as food, tinctures, aerosols, oils, or ointments), transfers, transports, sells, distributes, dispenses, or administers marijuana, products containing marijuana, related supplies, or educational materials to qualifying patients or their caregivers and is registered by the Department.

The FPCA's Recommendation: The State should allow for maximum local municipal control over (do not "preempt") the operation of "Medical Marijuana Treatment Centers (MMTCs). The State should allow local municipalities to set their own standards for critical issues such as zoning, location, hours, licensing, fees, security requirements, signage, and requirements of owner/operators, etc. In the alternative, the State should set minimum requirements but also leave as much reasonable discretion to local municipalities to decide on these critical issues for their residents.

The FPCA's Recommendation: The State should consider allowing individual municipalities to "opt out" of allowing MMTCs within their jurisdiction by democratic process – either a vote of the electorate or a vote of the governing body of the local municipality. See below sample language from the "opt out" provision in the state's implementing statute when medical marijuana dispensaries were first opening in Colorado:

“The operation of this article shall be statewide unless a municipality, county, city, or city and county, by either a majority of the registered electors of the municipality, county, city, or city and county voting at a regular election or special election called in accordance with applicable Florida law or a majority of the members of the governing board for the municipality, county, city, or city and county, vote to prohibit the operation of medical marijuana centers, optional premises cultivation operations, and medical marijuana-infused products manufacturers’ licenses.”

The FPCA’s Recommendation: The State should prohibit all edible products with THC because of the potential for abuse, as has occurred in other states. In the alternative, if edibles are going to be allowed, the State should create strict regulations, including:

- i. Restriction of edibles to single serving/dosage packaging.**
- ii. Prohibiting the addition of food coloring or artificial flavor to edibles.**
- iii. Requiring plain packaging of product that is child-proof and includes large warning labels with the accurate dosage amount.**

The FPCA’s Recommendation: Any person who is a qualifying patient or caregiver, or involved in the ownership or operation of a Medical Marijuana Treatment Center (MMTC), including as an owner, investor, employee, distributor or transporter of medical marijuana, should be issued a state photo ID card similar to current ID cards and drivers licenses. Law enforcement must have unlimited 24-hour access to an accurate, up-to-date state registry to confirm that a person is a registered patient or caregiver, or an MMTC owner, investor, employee, distributor or transporter of medical marijuana.

With regard to any person who is an MMTC owner, investor, employee, distributor or transporter of medical marijuana, no such state photo ID card should be issued unless the applicant has undergone and passed a background check by an authorized agency. No person in this category who has been convicted of a state or federal felony or convicted of a misdemeanor drug offense within the past 10 years should be issued such a state photo ID card or permitted to be in possession of medical marijuana.

If a person is in legal possession of medical marijuana but not carrying his/her medical marijuana state photo ID card, he/she should be subject to a non-criminal violation resulting in a \$250.00 fine, payable to the clerk of the court, and revocation of the state photo ID card and the authority to possess medical marijuana if the fine is not paid.

(Note: The background investigation described here should be conducted by either a state or local law enforcement agency. The cost of the background investigation should be borne by the applicant and paid up front, before the investigation is begun and without regard to the findings of the investigation.)

The FPCA's Recommendation: In the interest of full disclosure and to ensure that organized crime does not infiltrate the medical marijuana industry, all owners and investors in MMTCs in Florida should undergo a thorough financial background investigation. The designated state department or agency should be staffed and funded to perform these background investigations properly and efficiently.

The FPCA's Recommendation: The state photo ID card for patients, caregivers and MMTC owners, investors, employees, distributors and transporters of medical marijuana should be applied for and reissued every year.

(6) "Medical use" means the acquisition, possession, use, delivery, transfer, or administration of an amount of marijuana not in conflict with Department rules, or of related supplies by a qualifying patient or caregiver for use by the caregiver's designated qualifying patient for the treatment of a debilitating medical condition.

The FPCA's Recommendation: A person with a legal medical marijuana referral and a valid medical marijuana identification card, or a licensed medical marijuana caregiver may possess and transport medical marijuana in a motor vehicle upon the highways/roadways of the State of Florida. It should remain illegal to operate a motor vehicle in all circumstances in Florida under the influence marijuana.

(7) "Caregiver" means a person who is at least twenty-one (21) years old who has agreed to assist with a qualifying patient's medical use of marijuana and has qualified for and obtained a caregiver identification card issued by the Department. The Department may limit the number of qualifying patients a caregiver may assist at one time and the number of caregivers that a qualifying patient may have at one time. Caregivers are prohibited from consuming marijuana obtained for medical use by the qualifying patient.

(8) “Physician” means a person who is licensed to practice medicine in Florida.

(9) “Physician certification” means a written document signed by a physician, stating that in the physician’s professional opinion, the patient suffers from a debilitating medical condition, that the medical use of marijuana would likely outweigh the potential health risks for the patient, and for how long the physician recommends the medical use of marijuana for the patient. A physician certification may only be provided after the physician has conducted a physical examination and a full assessment of the medical history of the patient. In order for a physician certification to be issued to a minor, a parent or legal guardian of the minor must consent in writing.

The FPCA’s Recommendation: The “reasonable care” language here provides ample leeway for either the Legislature or the Department of Health to establish very specific regulations for doctors who issue a “physician certification” to a medical marijuana user. Because this has been an area of very substantial abuse by some physicians in Colorado in particular, any finding by a physician that a patient meets the Amendment 2 criteria for medical marijuana should be based on thorough examination, a record of substantive treatment by the physician over an extended period of time, and ample documentation of the illness and the justification for marijuana as a viable treatment option. The Department of Health should fund and staff a robust inspection program to ensure compliance, with robust civil penalties for physicians who fail to comply.

(10) “Qualifying patient” means a person who has been diagnosed to have a debilitating medical condition, who has a physician certification and a valid qualifying patient identification card. If the Department does not begin issuing identification cards within nine (9) months after the effective date of this section, then a valid physician certification will serve as a patient identification card in order to allow a person to become a “qualifying patient” until the Department begins issuing identification cards.

The FPCA’s Recommendation: The State should enact a specific statute or regulation that explicitly affirms law enforcement’s ongoing right to disclosure of whether a specific person is

a valid and currently licensed user or caregiver upon request. Law enforcement does not need to know the nature of any illness but must be able to confirm whether any marijuana is lawfully possessed.

The FPCA's Recommendation: Only individuals residing in the state of Florida for at least one year should be eligible to possess medical marijuana and to be issued a state photo ID card.

The FPCA's Recommendation: Any person who is a qualifying patient or caregiver, or involved in the ownership or operation of a Medical Marijuana Treatment Center (MMTC), including as an owner, investor, employee, distributor or transporter of medical marijuana, should be issued a state photo ID card similar to current ID cards and drivers licenses. Law enforcement must have unlimited 24-hour access to an accurate, up-to-date state registry to confirm that a person is a registered patient or caregiver, or an MMTC owner, investor, employee, distributor or transporter of medical marijuana.

With regard to any person who is an MMTC owner, investor, employee, distributor or transporter of medical marijuana, no such state photo ID card should be issued unless the applicant has undergone and passed a background check by an authorized agency. No person in this category who has been convicted of a state or federal felony or convicted of a misdemeanor drug offense within the past 10 years should be issued such a state photo ID card or permitted to be in possession of medical marijuana.

If a person is in legal possession of medical marijuana but not carrying his/her medical marijuana state photo ID card, he/she should be subject to a non-criminal violation resulting in a \$250.00 fine, payable to the clerk of the court, and revocation of the state photo ID card and the authority to possess medical marijuana if the fine is not paid.

(Note: The background investigation described here should be conducted by either a state or local law enforcement agency. The cost of the background investigation should be borne by the applicant and paid up front, before the investigation is begun and without regard to the findings of the investigation.)

The FPCA's Recommendation: The state photo ID card for patients, caregivers and MMTC owners, investors, employees, distributors and transporters of medical marijuana should be applied for and reissued every year.

(c) LIMITATIONS.

(1) Nothing in this section allows for a violation of any law other than for conduct in compliance with the provisions of this section.

(2) Nothing in this section shall affect or repeal laws relating to non-medical use, possession, production, or sale of marijuana.

(3) Nothing in this section authorizes the use of medical marijuana by anyone other than a qualifying patient.

(4) Nothing in this section shall permit the operation of any vehicle, aircraft, train or boat while under the influence of marijuana.

The FPCA's Recommendation: Given this explicit language in voter-approved Amendment 2, no level of THC should be permitted in a person operating a vehicle, aircraft, train or boat. It should be illegal to operate these conveyances while under the influence of any amount of THC. In the alternative, a reasonable standard for THC levels should be set by the state. If so, the FPCA recommends that the limit to operate a vehicle, aircraft, train or boat while under the influence marijuana should be less than 3 nanograms of THC / per ml of blood. Persons operating a vehicle, aircraft, train or boat at a level of 3 nanograms of THC / per ml of blood or higher should be subject to a presumption in any criminal prosecution that they were operating under the influence of THC in violation of Florida Statutes 316.193 (driving under the influence).

(5) Nothing in this section requires the violation of federal law or purports to give immunity under federal law.

(6) Nothing in this section shall require any accommodation of any on-site medical use of marijuana in any correctional institution or detention facility or place of education or employment, or of smoking medical marijuana in any public place.

The FPCA's Recommendation: The use of medical marijuana should not be allowed in or near public spaces, parks, schools, school buses, public transit facilities, or child care facilities, and use of medical marijuana shall comply with the provisions of the Florida Clean Indoor Air Act pursuant to Chapter 386, Part II, Florida Statutes and the Florida health initiative in section 20, Article X of the State Constitution. The State should enact legislation making explicitly clear that use of marijuana in violation of these provisions remains a criminal offense under existing law and that Amendment 2 provides no protection from prosecution for these activities.

The FPCA's Recommendation: Nothing shall require an employer to permit or accommodate the use, consumption, possession, transfer, display, transportation, sale, or growing of marijuana in any form, or to affect the ability of an employer to have a zero tolerance policy prohibiting the on-duty, and off-duty, use of marijuana, or prohibiting any employee from having a detectable amount of marijuana in such employee's system while at work.

(7) Nothing in this section shall require any health insurance provider or any government agency or authority to reimburse any person for expenses related to the medical use of marijuana.

(8) Nothing in this section shall affect or repeal laws relating to negligence or professional malpractice on the part of a qualified patient, caregiver, physician, MMTC, or its agents or employees.

(d) DUTIES OF THE DEPARTMENT. The Department shall issue reasonable regulations necessary for the implementation and enforcement of this section. The purpose of the regulations is to ensure the availability and safe use of medical marijuana by qualifying patients. It is the duty of the Department to promulgate regulations in a timely fashion.

(1) Implementing Regulations. In order to allow the Department sufficient time after passage of this section, the following regulations shall be promulgated no later than six (6) months after the effective date of this section:

a. Procedures for the issuance and annual renewal of qualifying patient identification cards to people with physician certifications and standards for renewal of such identification cards. Before issuing an identification card to a minor, the Department must receive written consent from the minor's parent or legal guardian, in addition to the physician certification.

b. Procedures establishing qualifications and standards for caregivers, including conducting appropriate background checks, and procedures for the issuance and annual renewal of caregiver identification cards.

c. Procedures for the registration of MMTCs that include procedures for the issuance, renewal, suspension and revocation of registration, and standards to ensure proper security, record keeping, testing, labeling, inspection, and safety.

d. A regulation that defines the amount of marijuana that could reasonably be presumed to be an adequate supply for qualifying patients' medical use, based on the best available evidence. This presumption as to quantity may be overcome with evidence of a particular qualifying patient's appropriate medical use.

The FPCA's Recommendation: The State should require specific and defined amounts of allowable possession to ensure proper enforcement. For example, "Any medical marijuana patient with a referral from a physician can possess up to two ounces of medical marijuana and cannot purchase more than two ounces of medical marijuana from a licensed medical marijuana facility in any 14-day period."

(2) Identification cards and registrations. The Department shall begin issuing qualifying patient and caregiver identification cards, and registering MMTCs no later than nine (9) months after the effective date of this section.

The FPCA's Recommendation: Any person who is a qualifying patient or caregiver, or involved in the ownership or operation of a Medical Marijuana Treatment Center (MMTC), including as an owner, investor, employee, distributor or transporter of medical marijuana,

should be issued a state photo ID card similar to current ID cards and drivers licenses. Law enforcement must have unlimited 24-hour access to an accurate, up-to-date state registry to confirm that a person is a registered patient or caregiver, or an MMTC owner, investor, employee, distributor or transporter of medical marijuana.

With regard to any person who is an MMTC owner, investor, employee, distributor or transporter of medical marijuana, no such state photo ID card should be issued unless the applicant has undergone and passed a background check by an authorized agency. No person in this category who has been convicted of a state or federal felony or convicted of a misdemeanor drug offense within the past 10 years should be issued such a state photo ID card or permitted to be in possession of medical marijuana.

If a person is in legal possession of medical marijuana but not carrying his/her medical marijuana state photo ID card, he/she should be subject to a non-criminal violation resulting in a \$250.00 fine, payable to the clerk of the court, and revocation of the state photo ID card and the authority to possess medical marijuana if the fine is not paid.

(Note: The background investigation described here should be conducted by either a state or local law enforcement agency. The cost of the background investigation should be borne by the applicant and paid up front, before the investigation is begun and without regard to the findings of the investigation.)

The FPCA's Recommendation: In the interest of full disclosure and to ensure that organized crime does not infiltrate the medical marijuana industry, all owners and investors in MMTCs in Florida should undergo a thorough financial background investigation. The designated state department or agency should be staffed and funded to perform these background investigations properly and efficiently.

The FPCA's Recommendation: The state photo ID card for patients, caregivers and MMTC owners, investors, employees, distributors and transporters of medical marijuana should be applied for and reissued every year.

(3) If the Department does not issue regulations, or if the Department does not begin issuing identification cards and registering MMTCs within the time limits set in this section, any Florida citizen shall have standing to seek judicial relief to compel compliance with the Department's constitutional duties.

(4) The Department shall protect the confidentiality of all qualifying patients. All records containing the identity of qualifying patients shall be confidential and kept from public disclosure other than for valid medical or law enforcement purposes.

The FPCA's Recommendation: Create, staff, and fund a statewide Marijuana Enforcement Division. Include provisions to address the need for local law enforcement training.

The FPCA's Recommendation: The state should permit a reasonable tax on the sale of Medical Marijuana that is sufficient to raise revenue needed to support a new Medical Marijuana Enforcement Division at the state level and to support the additional staff and any other state or local agencies that are given new responsibilities to ensure the lawful and proper regulation of Medical Marijuana.

(e) LEGISLATION. Nothing in this section shall limit the legislature from enacting laws consistent with this section.

The FPCA's Recommendation: The State should fund appropriate statewide training of local law enforcement officers on medical marijuana, including Amendment 2 and its accompanying infrastructure, regulations and mechanisms for enforcement and accountability of all parties.

The FPCA's Recommendation: No "homegrown" medical marijuana should be allowed. The State should enact legislation making explicitly clear that growing of marijuana in any location not authorized and sanctioned by the Department of Health remains a criminal offense under existing law and that Amendment 2 provides no protection from prosecution for this activity.

(f) SEVERABILITY. The provisions of this section are severable and if any clause, sentence, paragraph or section of this measure, or an application thereof, is adjudged invalid by a court of competent jurisdiction other provisions shall continue to be in effect to the fullest extent possible.

Sheriff Bob Gualtieri

Sheriff Bob Gualtieri began his career with the Pinellas County Sheriff's office approximately 35 years ago. He was appointed as sheriff in 2011 and elected and re-elected in 2012 and 2016, respectively. Sheriff Gualtieri serves on the board of directors of the Florida Sheriffs Association (FSA) and is chair of the FSA Legislative Committee. He earned his bachelor's degree from Eckerd College in St. Petersburg and his law degree from Stetson University College of Law.

Lieutenant Colonel Michael Thomas

Lieutenant Colonel Michael Thomas graduated from the Florida Highway Patrol 79th Basic Recruit Class on May 5, 1987. In his 29 years as a member, he has served in six of the ten Patrol Operations Troops, starting with his first assignment in Davie. In 2011, he was promoted to Major as the Troop Commander for Troop C, Tampa. In October 2015, he was appointed to the position of Lieutenant Colonel/Deputy Director of the Patrol. In addition, Lt. Colonel Thomas holds a B.A. in Public Administration from Barry University and a Master's Degree from the prestigious Naval Post Graduate School in Homeland Security.