



2024 Massachusetts Convention Workshop

Rescheduling

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**Slides 6 through 15 provided with appreciation and assistance from Attorney David Holland*

Mike Ross

Michael P. Ross is the co-chair of the Cannabis Practice Group and a member of the Real Estate Group. He brings years of experience as a commercial real estate attorney, and previously, as a former elected official, to solving complex problems for his clients.

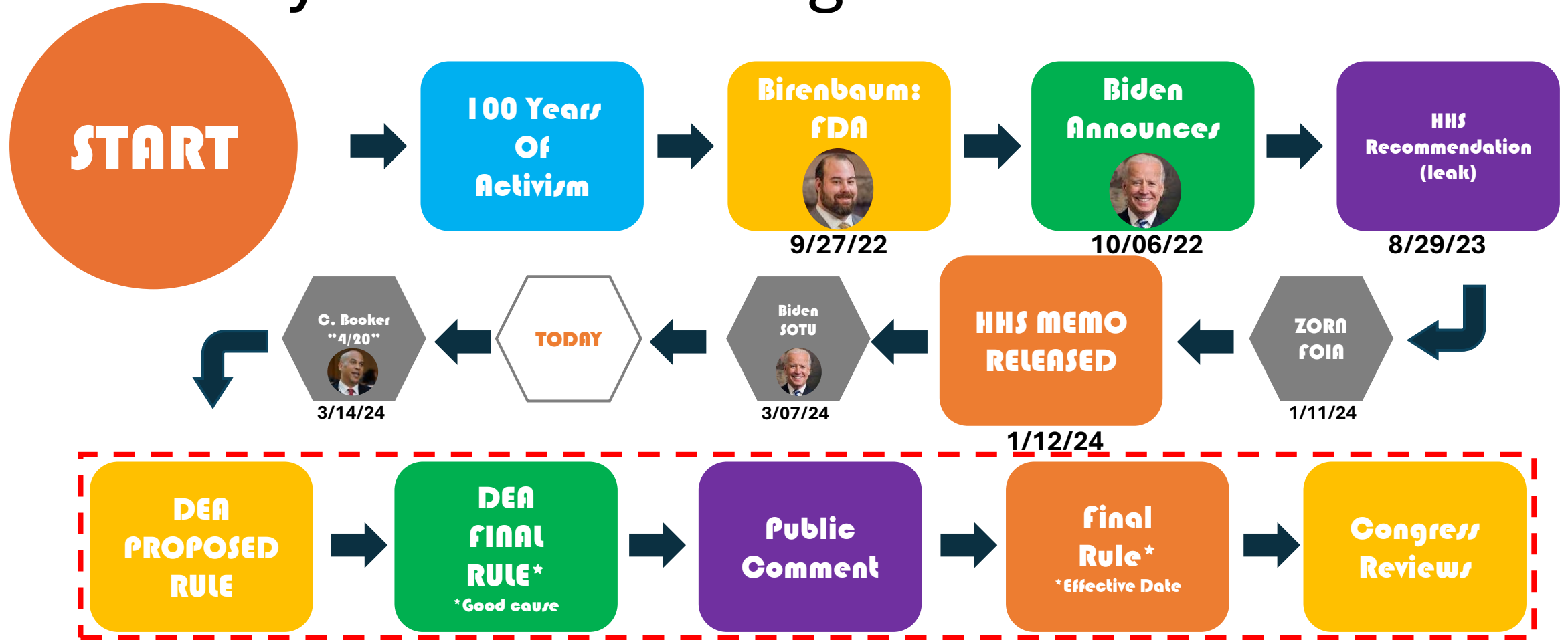
Mike's legal practice has focused on the successful permitting of commercial real estate projects throughout Boston and beyond. He has permitted residential and commercial project in all the neighborhoods of Boston, including historic neighborhoods and empowerment communities. He also has permitted numerous Cannabis Entities including Boston's first adult-use retail establishment. Together with the Cannabis Practice Group, the team also assisted in the opening of the state's first retail business, both in Massachusetts and in New York. He regularly appears before government boards and agencies in order to advance the needs of his clients.

Mike is a regular speaker on panels and conferences, discussing the experiences he has gained as an attorney. He regularly presents to Bar Associations and CLE courses for fellow practitioners, as well as serves as a speaker at industry events. He has authored several guidance documents for the use of fellow attorneys.

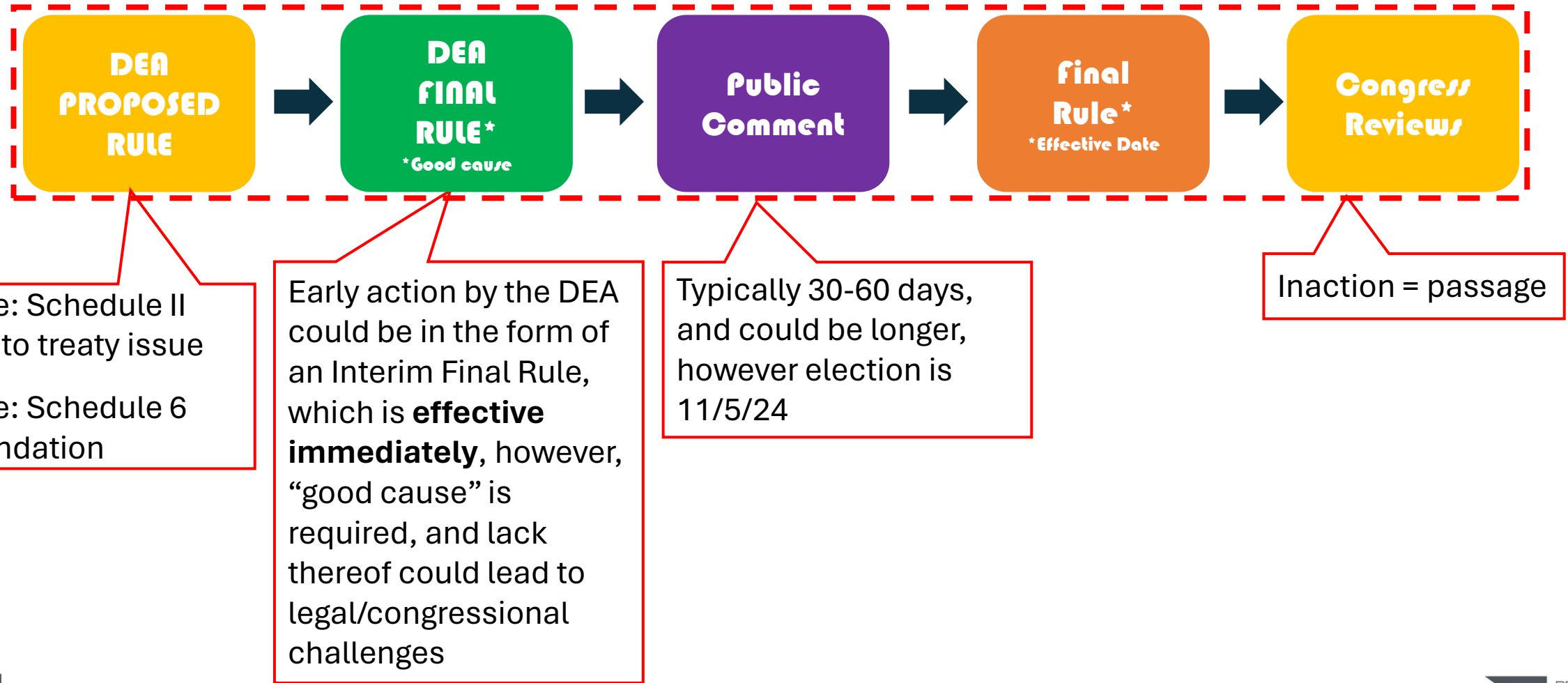
Mike served for 14 years as a Boston City Councilor, and was President of the body from 2009 to 2010. In 2013, he entered the race for mayor, sharing a bold vision for the city's future. Mike holds a bachelor's degree from Clark University in Worcester, an MBA from Boston University, and a law degree from Suffolk University. He is a regular contributor to various publications including *The Boston Globe*, *Boston Magazine* and *Politico*. He and his wife live in East Boston.



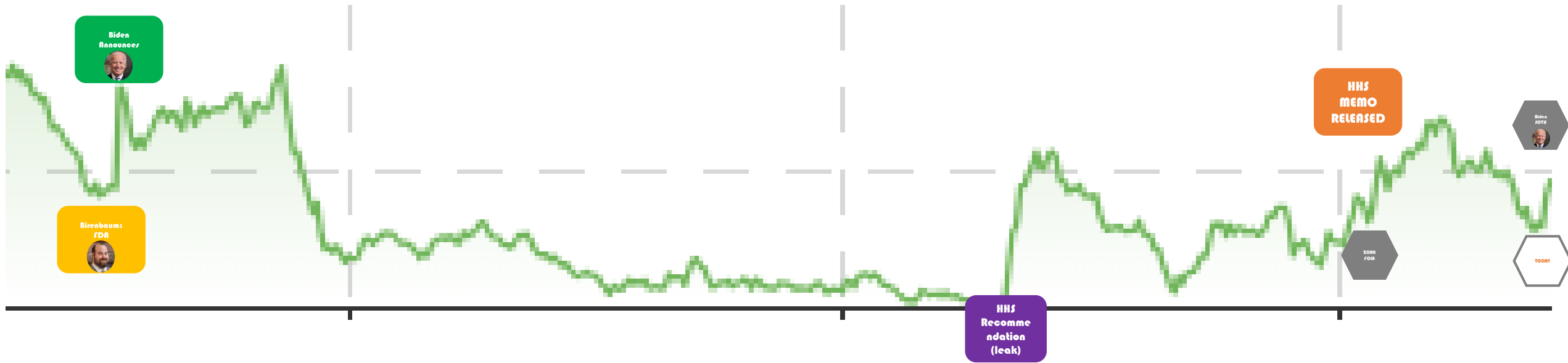
History of Rescheduling



History of Rescheduling (Continued)



Stock Performance



HHS Recommendation

The Recommendation from HHS to DEA 8/29/2023:

“Upon consideration of the eight factors determinative of control of a substance under 21 U.S.C. 811(c), the Food and Drug Administration (FDA) recommends that marijuana be placed in Schedule III of the CSA. The National Institute on Drug Abuse has reviewed the enclosed documents (which were prepared by FDA’s Controlled Substance Staff and are the basis for FDA’s recommendation) and concurs with FDA’s recommendation. Marijuana meets the findings for control in Schedule III set forth in 21 U.S.C. 812(b)(3). Based on my review of the evidence and FDA’s recommendation, it is my recommendation as the Assistant Secretary for Health that marijuana should be placed in Schedule III of the CSA.”

Rachel L. Levine, M.D.

Assistant Secretary for Health

Drug Scheduling under CSA (21 USC 812)

- A. There is ascending order of substances from most dangerous to least in Schedules I-V – 21 USC 812(a)
- B. Schedule I criteria: – 21 USC 812(b)(1)(a-c)
 - i. High Potential for Abuse
 - i. “**Abuse:** The intentional non-therapeutic use of a drug, **even once**, to achieve a desired psychological or physiological effect.”
 - ii. No currently acceptable medical use (CAMU) – HHS Recommendation included 4 factor test for CAMU
 - i. Whether there is evidence that taking the drug can occur in amounts sufficient to create a hazard to their health or to the safety of the community.
 - ii. Whether there is significant diversion of the drug or drugs from legitimate drug channels.
 - iii. Whether individuals are **taking the drug on their own initiative rather than on the basis of medical advice from a practitioner licensed to administer such drugs in the course of his professional practice.**
 - iv. Whether a similar drug containing such substance or similar substance is already listed on the Schedules as having a potential for abuse to make it likely that the drug will have the same potentiality for abuse, thus making it reasonable to assume that there may be significant diversions from legitimate channels, **significant use contrary to or without medical advice**, or that it has a substantial capability of creating hazards to the health of the user or to the safety of the community
 - iii. Lack of safety for the use of the drug under medical supervision
 - iv. Can't research without stringent control
 - i. Only University of Mississippi has been authorized since 1970 to grow and study same strain of cannabis
 - ii. 10 or so long -term patients in the program

Pathways to Rescheduling

- A. Petition HHS/FDA/DEA to reschedule
- B. Administratively by Attorney General, HHS, FDA, and DEA

Drugs may be rescheduled by US Attorney General subject to the procedures set forth in 21 USC 811 and recommendation of the Secretary of Health and Human Services (HHS) after review by Drug Enforcement Administration (DEA) and binding recommendation from Food and Drug Administration (FDA) to Attorney General

Division of Labor:

“The Secretary of HHS has delegated his duties in this regard to the Food and Drug Administration ("FDA"), which has assigned the actual preparation of the evaluation and scheduling recommendation to the Controlled Substances Staff ("CSS") within its Center for Drug Evaluation and Research ("CDER")”

- *Pennington/Zorn.*

DEA Review

Once DEA receives the HHS recommendation, which is binding upon it with regard to matters of medicine and medical issues (*21 USC 811(b)*), it then determines whether there is “substantial evidence” to justify continuing the existing scheduling designation, rescheduling, or descheduling.

- A. At outset, in accordance with 21 USC 811(b), DEA must:
 - 1. “Gather the necessary data”
 - 2. Request scientific and medical evaluation from HHS
 - 3. Request a scheduling recommendation from HHS (done in 2023)
- B. DEA must then determine whether there is “substantial evidence” to justify continuing the existing scheduling designation, rescheduling, or descheduling. 21 USC 811(b).

DEA Review (Continued)

21 USC 812(c) - “In making any finding under subsection (a) of this section or under subsection (b) of section 812 of this title, the Attorney General shall consider the following factors with respect to each drug or other substance proposed to be controlled or removed from the schedules:

- (1) Its actual or relative potential for abuse.
- (2) Scientific evidence of its pharmacological effect, if known.
- (3) The state of current scientific knowledge regarding the drug or other substance.
- (4) Its history and current pattern of abuse.
- (5) The scope, duration, and significance of abuse.
- (6) What, if any, risk there is to the public health.
- (7) Its psychic or physiological dependence liability.
- (8) Whether the substance is an immediate precursor of a substance already controlled under this subchapter.

Traditionally, for a drug to have a ‘currently acceptable medical use’ it must have been approved by FDA as a drug that can be marketed and sold in interstate commerce. *Pennington/Zorn*

Despite enduring medical cannabis programs established in 37 states, because of federal prohibition, those programs are necessarily siloed and therefore FDA has not approved cannabis for marketing and interstate commerce. *Pennington/Zorn*

Note: DEA has denied petitions in 2001, 2011, 2016. *R. Mao*

Treaty Concerns with Rescheduling

Even with significant evidence that should militate DEA to recommend removal of cannabis from Schedule I, politics, may prevail over science yet again due treaty obligations of the United States imposed under the Single Convention on Narcotic Drugs of 1961

Under 21 USC 811(d)(1):

“If control is required by United States obligations under international treaties, conventions, or protocols in effect on October 27, 1970, the Attorney General shall issue an order controlling such drug under the schedule he deems most appropriate to carry out such obligations, ***without regard to the findings required by subsection (a) of this section or section 812(b) of this title and without regard to the procedures prescribed by subsections (a) and (b) of this section.***”

Many signatory countries to that treaty have or are considering international cannabis commerce .



DEA Review (Continued)

Once DEA concludes its investigation and determination it will publish a proposed rule in the Federal Register announcing its investigation and findings along with those of HHS and the documents relied upon including the analysis of both organizations under the 8-factor test listed below. *21 USC 812*.

After publishing the proposed rule there is a public comment period and the possibility of public hearings on any recommendation or determination conducted by an Administrative Law Judge (ALJ) under the Administrative Procedures Act (APA) pursuant to *5 USC 556 et seq.*

ALJ at the conclusion of the hearing may then issue a final ruling on the scheduling determination and that may be appealed within 30 days of the final decision by an 'aggrieved party' in the DC Circuit Court of Appeals or other federal appellate jurisdiction where the aggrieved's place of business is located. *21 USC 877*.

Immediate Effects of Rescheduling

A. Removes IRS Code 280E which pertain to Schedule I and II substances.

B. Removes federal drug trafficking crimes under 21 USC which pertain to Schedule I and II substances and impose draconian sentences.

C. It does not remove it altogether from federal criminal penalties. 21 USC 844(a).

i. Even placed in Schedule V would still amount to federal criminal diversion charges if distributed for any purpose other than medical and significant sentencing exposure under the federal sentencing guidelines. *21 USC 829(a) and (c)*.

1. *21 USC 844(b)(1)(B)(vii)* – 100 to 1000 Kgs of Cannabis Mandatory 5-40 year sentence

2. *21 USC 844(b)(1)(A)(vii)* – more than 1000 kgs of Cannabis – Mandatory Sentence 10-Life Imprisonment

Immediate Effects of Rescheduling (Cont.)

- D. Interstate commerce of medical cannabis
- E. Would remove significant barriers to scientific research which could be conducted without stringent guidelines from federal government and DEA.
- F. Would legalize cannabis banking at least for the medical industry

Musings

- A. Rescheduling vs. Descheduling
- B. What does the new regime look like?
- C. What happens to Adult Use currently in 23 states?
- D. If Cannabis = Pharmaceutical = Tax Exempt, what happens to City/State revenues?
- E. What happens to Social Equity programs?
- F. BUT the end of 280E



Musings (Continued)

	Mike's Cannabis Pre-Rescheduling	Mike's Cannabis Post-Rescheduling	Difference
Gross Revenue	\$10,000,000	\$10,000,000	0
Cost of Goods Sold	\$4,000,000	\$4,000,000	0
Business Expenses	\$4,000,000 (\$0 allowed)	\$4,000,000	\$4,000,000
Taxable Income	\$6,000,000	\$2,000,000	\$4,000,000
Federal Tax*	\$2,340,000	\$780,000	\$1,560,000
Net Revenue	(\$340,000)	\$1,220,000	\$1,560,000

