Holly Griffin: Thank you for attending Changes in Federal Approaches to Cannabis: Process and Impact, part of our 2023 Summer Cannabis Regulatory Deep Dive. The event is hosted by the Drug Enforcement and Policy Center at The Ohio State University, Moritz College of Law. Before we begin, we have just a few notes we’d like to share with you. First, we want to draw your attention to the Q and A function at the bottom of the zoom window.

Holly Griffin: The chat is disabled, but you may submit questions at any time. Please note, however, that there is limited time available for Q and A during the webinar. Second, closed captioning has been enabled for this event. To change how you view the transcription or to hide it, click show caption in the menu at the bottom of your zoom window. Finally, this event is being recorded. The recording will be made available on the event page and social media channels as soon as possible after the event.

Holly Griffin: Follow us @OSULawDEPC to stay up to date on our research, programming and future events. Thank you again for joining us, and we hope you enjoy the event. Cat?
Cat Packer: Thank you so much.

Cat Packer: Hello. My name is Cat Packer. I am a practitioner in residence here at The Ohio State University Moritz College of Law Drug Enforcement and Policy Center. And I also serve as the director of drug markets and legal regulation at the Drug Policy Alliance.

Cat Packer: I'd like to welcome folks to today's program, titled Changes in Federal Approaches to Cannabis Process and Impact. Before we get started, I'd like to thank the Drug Enforcement and Policy Center for their ongoing efforts to help shape and enrich public conversations about the intersecting fields of criminal justice and drug policy and enforcement and their historical and modern impact on society.

Cat Packer: The center as well as its leadership, including Doug Berman, who served as my former law, professor.

Cat Packer: And it's the centers executive director are doing amazing and constructive work.

Cat Packer: As a graduate of the law school, it's been a rewarding experience to be able to continue partnering with the university as a practitioner.

Cat Packer: For today's conversation, I would like to do a little bit of screen sharing, so I'm going to see if I can try and get technology to work with me today.

Cat Packer: So speaking of some of the work that the center has been constructive in supporting, I'd like to take a a brief moment to talk about

Cat Packer: a recent publication that was supported both by the Center and the Drug Policy Alliance, which I published last month. This publication is titled An Equity Action Plan for Marijuana: The Biden Administration's Opportunity to Advance Equity through Cannabis Reform.

Cat Packer: In this paper I explore President Biden's executive orders on equity, which define equity as the consistent and systematic, fair, just, impartial treatment of all individuals, and these executive orders direct Federal agencies to
develop equity action plans or, as the Biden Administration describes them, first of their kind roadmaps to address the barriers and discrimination that under served community face.

Cat Packer: Beyond exploring the equity action plans, in this paper I discuss how they're foundational to the Administration’s goal of advancing equity across all federal policies and programs. And I draw attention to the fact that none of the 90 equity action plans submitted by Federal agencies mention marijuana reform, despite the Biden Administration acknowledging racial disparities.

Cat Packer: I appreciate the center supporting me and putting out this publication, I'll make sure that I drop the link to this publication in the chat. In particular, because in this publication I suggest that an Equity Action Plan could help inform the Administration's action on marijuana reform. In part it could help inform DOJ guidance, for example,

Cat Packer: or could potentially help inform what we'll be discussing today, which is the administrative review of how cannabis is scheduled

Cat Packer: As the director of drug markets and legal regulations for the Drug Policy Alliance and as a reform advocate, it's important to me that the Government not only change its approach on marijuana, but that these changes specifically end and address the harms of criminalization and address barriers. And so I'd really like to again thank the center for for their support and for panelists today for

Cat Packer: allowing us to have a conversation, a constructive conversation not only about the process that's at hand in terms of scheduling, but it's potential impact.

Cat Packer: Today, I have assembled a group of leading experts and practitioners and I'd like to now take a brief moment to ask them to introduce themselves and share how they have become familiar with the marijuana status under Federal law. And I'm looking at my screen, so I'll start with Shane.

Shane Pennington: I'm really excited to be here.

Shane Pennington: I'm Shane Pennington. I'm a partner at
Shane Pennington: Porter Wright in Washington, DC. I began my career after clerking for a few Federal judges, including on the DC Circuit, where I got a lot of experience with administrative law and administrative processes.

Shane Pennington: In the Supreme Court Practice group of a large law firm focusing on administrative law issues and challenging agency action, and through a pro bono case I got involved with some of the research barriers challenging some of the research barriers associated with the NIDA monopoly which we eventually, after 3 lawsuit, succeeded in ending.

Shane Pennington: And at that point decided, you know what I really like this area of law and I think there's a lot of important work to do. And so I, kind of change my career path to focus on controlled substances issues and drug policy reform at the Federal level.

Fatima Afia: Hi! I'm Fatima Afia. I am an attorney at Rudick Law Group, PLLC. I first came to the industry as a litigator. I was part of a legal team that brought a lawsuit entitled Washington vs. Sessions. That then became Washington vs. Barr and that was a Federal lawsuit against the DOJ and the DEA that sought a declaration of the control substances act as it applies to cannabis as unconstitutional.

Fatima Afia: on a number of different claims, including that you violated the Fifth Amendment right to due process equal protection, fourteenth amendment as well, right to travel. And so, as part of that legal team, we actually will appealed to the United States Supreme Court. But before that we had appeal to the Second Circuit Court of Appeals.

Fatima Afia: and in that process it became really clear to us that the descheduling versus rescheduling debate was really crucial in terms of how we were going to proceed, because whenever you bring a lawsuit against a Federal or State agency, you do have to what's called exhaust your administrative remedies and so we had to make a decision on whether or not we were going to actually do that.
Fatima Afia: And my work in that lawsuit really open my eyes to the entire process of the scheduling versus rescheduling before the DEA. And you know I can talk a little bit more in depth about that experience as we go through this panel. But that's sort of how I came to the industry. And then I transitioned over more into the commercial transaction side of the space. And so now you know, my work focuses primarily on public policy, advocacy work, regulatory compliance, licensing and application work as well as corporate

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Fatima Afia: law. And so I'm really excited to be joining all of you guys today. Thank you for having me.

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Cat Packer: Thank you. John?

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John Hudak: Thank you, Cat. Good afternoon, everyone. My name is John Hudak. I'm currently the director of the Office of Cannabis Policy for the State of Maine, where I serve as the State's Chief Regulator and Chief Enforcement Officer for the medical and adult use cannabis programs. Prior to joining OCP about 6 months ago I was a senior fellow at the Brookings Institution, where I led the institutions research into cannabis policy and politics.

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Cat Packer: Thank you so much, John. Rob?

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Robert Mikos: Hello, everyone, thanks for having me. Thanks, Cat, for moderating this discussion. my name is Rob Mikos. I'm a law professor at Vanderbilt University, down in Nashville, Tennessee, which still has, I'm sorry to say, some of the the most restrictive cannabis laws in the nation.

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Robert Mikos: I've actually been working on this issue at different institutions now for probably more than 15 years, working in kind of probably defined the cannabis law field. I I have a particular interest and expertise in a lot of the power issues that surround this field. That the power of different government actors, be they local,

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Robert Mikos: state, federal, or international, to shape our our cannabis law policy. And that's sort of my hook for this particular panel.

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Cat Packer: Thank you, Rob. And Patti?

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Patti Zettler (she/her): Hi, everyone. Thanks, Cat, for moderating, and thanks to my panelists and all of you for being here. I think it'll be a really interesting discussion.

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Patti Zettler (she/her): My name is Patti Zettler. I'm a law professor at The Ohio State University. And I'm a faculty member of the Drug Enforcement and Policy Center here as well as the Cancer Control Program at Ohio States, James Comprehensive Cancer Center. My research and teaching focus on administrative law, FDA and public health law. And before academics, I was, I served as an associate chief counsel in the office of the Team

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Patti Zettler (she/her): Council at FDA. So I come at this from a public health law and FDA perspective.

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Cat Packer: Well, thank you. Thank you all again for joining me for today's panel. Part of the reason why I wanted to assemble this group is because there's so much chatter happening right now about the Biden Administration Scheduling Review.

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Cat Packer: And I've been working over the course of the last several months to better understand the scheduling process. To better understand its impact. And as I've connected with different stakeholders that are impacted or involved in the process, it just seems like there are so many different questions that remain.

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Cat Packer: So, I appreciate being able to to sit in the seat where I'm asking questions at this time. And hopefully, through today's conversation, both attendees and members of the public can have a better understanding of what's at stake.

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Cat Packer: So part of what I'd like to be able to discuss in whole today are the implications of marijuana status under Federal law, the ongoing process that could change marijuana status under Federal law, and the implications and difference between rescheduling and descheduling marijuana.

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Cat Packer: Although there are 38 states now that have medical programs or authorized cannabis for medical use, and I believe 23 states today that have authorized cannabis for adult use. Cannabis still remains criminalized at the Federal level, and I know that whether we're looking at this from a academic perspective, from the perspective of a regulator or practitioner, or just a a consumer,

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Cat Packer: or or patient, I understand that the consequences of rescheduling and descheduling are enormous. And all signs indicate that a shift is imminent.
Cat Packer: In October, President Biden made a statement on marijuana reform where he announced 3 steps that he was taking to quote end the country's failed approach to marijuana. Part of these steps were to announce a pardon of

Cat Packer: individuals with Federal marijuana possession charges for simple possession, urging governors to do the same and also asking the Secretary of Health and Human Services and the Office of Attorney General to begin review, of how marijuana is scheduled under Federal law. I'm eager to jump into the administrative process itself,

Cat Packer: but I think it'd be helpful to start with some context, and some historical context specifically, to get a better understanding of how marijuana ended up as a scheduled substance in the first place. And so I'm gonna ask John if you can give us a little bit of history to talk about the criminalization of cannabis at the Federal level. How did we get here?

John Hudak: Yeah, thank you, Cat. You know, the Controlled Substances Act really lays out a fairly robust scientific procedure by which the administrative agencies of the Federal Government consider where substances belong in terms of Federal control, and that has been fairly effective for most of the history of the CSA. However, the earliest part of the CSA, that is, the Congressional aspect, the an initial passing of CSA

John Hudak: blended what I would consider science, pseudoscience, and politics to make the determinations among about those original designations, the original scheduling decisions. And so when we look at some of the original choices that Congress makes a made with other substances, you can see real scientific value, real scientific information being built into those decisions.

John Hudak: And then there are other substances, and cannabis certainly falls into that other substance category. The decision by Congress was driven largely by a decades long propaganda campaign by the Federal government, by non federal entities, by law, enforcement by advocacy, organizations
John Hudak: to scare, to frankly to scare the hell out of Americans about what the substance was, what it could do to society, what it could do to in individuals. And so in a lot of ways, it ended up being an easy decision

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John Hudak: for Congress to say

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John Hudak: this is one of the worst substances in our society. Why? Not because the American Medical Association said that, not because leading researchers into the substance said that, but because political actors conveyed this over and over again and political actors inside and outside of government to scare Americans and to scare their elected officials and representatives. And so ultimately,

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John Hudak: cannabis became the Boogie Man of of much of the twentieth century. And in that sense it wasn't a surprise that it ended up as a schedule one substance. And of course, attached to its schedule one substance status is the criminalization aspect to it. And what we know very explicitly

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John Hudak: was that President Nixon, who signed the Controlled Substances Act into law, saw cannabis as a politically opportunistic, divisive subject that could impact his political enemies, as he called them.

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John Hudak: And this was also something that other politicians, not just Richard Nixon, people in Congress, governors, etc., saw this as an opportunity to enact a type of political will through criminalization against people who frankly didn't

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John Hudak: intend on voting for some of those people. And so a really nasty stew of politics came together to put cannabis as a schedule one substance.

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Cat Packer: Thanks, thanks for some of that history, John. Part of the context that, I think is is helpful for folks to understand here is that, you know, since cannabis has been placed on the Controlled Substances Act as a schedule on substance,

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Cat Packer: we've come to learn that Nixon's former domestic policy chief is known to have said, and I'll quote, "you understand what I'm saying we couldn't make it illegal to be either against the war or black,"
Cat Packer: but by getting the public to associate the Hippies with marijuana and blacks with heroin, we could criminalize both heavily, we could disrupt those communities, we could arrest their leaders, raid their homes, break up their meetings, and vilify them night after night on the Evening News.

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Cat Packer: Did we know we were lying about the drugs? Of course we did." Just for historical context and part of what I also think is interesting is I've been exploring this topic is the fact that it seems as though marijuana's placement as a scheduled one substance, was originally supposed to be temporary

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Fatima Afia: Sure? Yeah. So that's absolutely correct. The CSA actually created what's called the Commission on Marijuana and Drug Abuse which we now know as the Shafer Commission and

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Fatima Afia: part of the enactment of that commission as part of the CSA was that there were supposed to be 9 members appointed by the President of the United States, 2 members by the Speaker of the House of Representatives, and 2 members appointed by the President of the Senate. And so, of course, President Nixon gets the most members appointed to this commission, including the Chair of the Commission, who is Raymond Shafer, and so he does appoint the Commission.

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Fatima Afia: Under the CSA, the Commission has one year from receipt of funding for a study on the connection between cannabis use and aggressive behavior to see the extent of cannabis using the United States at that time, understanding how many people are actually using, how many people are getting arrested for its use.

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Fatima Afia: All those sorts of data together, and also understanding what the efficacy of existing Federal drug laws had been with respect to cannabis. And so this study was supposed to be completed within a year from the date that they received funding in order to commission it, and they were supposed to come out with a report. And so they did. In 1972, the Shafer Commission did come out with the report

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Fatima Afia: and among its findings was, of course, that cannabis was not anywhere near as dangerous as we had been made to believe through reefer madness propaganda, as John alluded to, it did not create violent behavior. And the Shafer Commission actually recommended that they
Fatima Afia: decriminalize on both the Federal and State level, simple possession of cannabis, and they also encouraged further medical research on the cannabis plant to understand its real medical efficacies, it's real medical applications. And, of course, the Nixon Administration in light of its racist and political motivations behind even placing cannabis under schedule one, ignored completely all of these findings. And nothing was ever done to change the current classification of cannabis under schedule one.

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John Hudak: Cat, could I? Could I jump in quickly? I I I loved everything that Fatima said, but I wanted to share a quick anecdote. After after my book on cannabis first came out I was sitting at my desk at Brookings, and I got a cold call from someone, and I, rare as I rarely do, actually answered it, and it was a it was a relative of of Ray Shafer's.

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John Hudak: And he called, and he said, hey, I read your book, and I really appreciated the way that you treated my family member in this book. And I said, oh, you know those. It's very kind words. He said, you know I I want to tell you a story. My, it was his grandson, he said my grandfather had a pretty illustrious career. He was Governor of Pennsylvania, and he was a good friend of Richard Nixon he said. And in toward the end of his life,

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John Hudak: he told family members of his that one of his proudest moments was standing in the Oval Office being berated by President Nixon about this report and standing his ground and refusing to retract the report. That's the type of political environment that this report existed in, and one of Richard Nixon's good friends had to stand there and just say, no, Mr. President, we're moving forward with this report.

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Cat Packer: I appreciate that, John, that I think that all of that context is really helpful for the conversation and where we are at present day.

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Cat Packer: So I'd like to shift for a moment and talk about what it would be talking about when we're talking about marijuana being a controlled substance, because I know that the Farm Bill passed, and it seems like, now there's a legal distinction. There's certain parts of cannabis that aren't scheduled. Shane, can you talk a little bit about what exactly is is controlled? And how is hemp

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Shane Pennington: Sure. So technically, cannabis is not a schedule one substance. The schedule one substance is marijuana with an H, or now a J. They actually amended the definition recently to add that J. And when you look at that
definition, it's awfully technical. And the reasons for the technicality of the definition derive from U.S. treaty considerations that sort of motivated much of the, you know, background and sort of fundamental

Shane Pennington: you know, impetus for passing the CSA in the first place.

Shane Pennington: And so marijuana is defined

Shane Pennington: as certain parts of the cannabis plant. And then

Shane Pennington: there's a statutory exemption. It it says, you know, all the parts of the camps plant except mature stocks, the fiber of the stocks, the seeds that aren't capable of germination, oil, resin derived from those seeds, and and all these different

Shane Pennington: you know, sort of rifle shot exemptions. Then, after that, the definition also exempts hemp, and that hemp exemption

Shane Pennington: came from the 2018 Farm Bill. And that

Shane Pennington: basically defined hemp

Shane Pennington: to be

Shane Pennington: cannabis, the cannabis plant, and any part of the cannabis plant, including derivatives and and so forth that is below 0.3% delta 9 Tetrahydrocannabinols on a dry weight basis.
Shane Pennington: And so there are certain exemptions.

Shane Pennington: The ones that are in the definition of marijuana and the CSA that do not have a 0.3% limit. So theoretically, you could have a mature stock with a hundred percent delta 9 THC, and it would not be marijuana, and it would not be a schedule one substance.

Shane Pennington: But you know that doesn't occur in nature, at least not yet. No, no biologist has, or you know has figured that one out. But then there, for the rest, you know, that actually is within the definition of marijuana that's not exempt under the definition.

Shane Pennington: If any of that stuff is below 0.3% delta 9 on a dry weight basis,

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Shane Pennington: epidiolex is descheduled, our bad, but they don't say our bad. They just deschedule it. And they don't explain the treaty situation which I find intriguing.

Shane Pennington: But yeah, that's kind of where we stand. It's incredibly complicated. But basically hemp is out. Which means anything below 0.3%, and then other stuff is out, regardless of if it has point 3 or more and there are certain pharmaceuticals that are, that have been approved and therefore aren't in schedule one.

Cat Packer: So it's just a little complicated.

Shane Pennington: Yes.

Cat Packer: Okay, great.

Robert Mikos: Yeah, it's it's a key question on why, why, we're spending so much time on scheduling. It's really because scheduling determines how a substance is going to be regulated under the CSA.

Robert Mikos: So substances that are placed on schedule one, they are the most tightly controlled substances. As you move down the schedule to schedule 2, 3, 4, 5, and so on they become less tightly controlled progressively.
Robert Mikos: So the fact that marijuana has been placed on schedule one means, as a practical matter, that almost any activity involving marijuana, again, not hemp, but marijuana is going to be prohibited under federal law.

Robert Mikos: That includes simple possession of marijuana. It includes cultivation. It includes processing, and it includes a distribution and and sale of course. All those activities are banned because of, that's a natural implication of its schedule one status. Really the only thing you can do with marijuana lawfully under Federal law, is you can administer it pursuant to a federally approved research trial. That's really the extent of activities that are legal under Federal law. To be sure, under Federal law it may be legal.

Robert Mikos: but the DOJ isn't really enforcing that prohibition right now, just as a voluntary matter. We also, when it comes to medical marijuana, Congress has forbidden the agency from enforcing the Federal ban against individuals who are acting in compliance with State medical marijuana programs.

Robert Mikos: But there are also, notwithstanding that DOJ forbearance and the spending riders that Congress has adopted,

Robert Mikos: they're also some ripple effects that them out from a marijuana schedule one status. Those include things like tax ramifications. So even if you're a fully law compliant, state law compliant medical marijuana operator, you still pay exorbitant taxes under Federal law because of an obscure provision in the Federal tax code known as Section 280E.

Robert Mikos: You still struggle to get basic banking services because banks don't want to handle the money of this industry, because even if the operators aren't being prosecuted, all that money is dirty, all of it is represents the proceeds of unlawful activity.
Robert Mikos: So there, there are all these different consequences, we could talk about, you know, dozens of other consequences that stem from marijuana schedule one status, you can see why this is such an important thing, why the the scheduling of a substance is so critical in determining how it's going to be regulated, at least under the Controlled Substances Act under Federal law.

Cat Packer: Thanks, Rob. That's really helpful to understand specifically some of the ramifications of the Controlled Substances Act. But, as I understand, there is another body of law at the federal level that controls marijuana, cannabis as well. Patti, can you talk a little bit about

Cat Packer: those laws?

Patti Zettler (she/her): Sure. So what Cat is alluding to is the Federal Food Drug and Cosmetic Act, which is FDA's enabling statute and

Patti Zettler (she/her): I think if there is one thing you all take away from today about FDA and cannabis, I would say, take away that whatever schedule a drug is in, or total descheduling, does not change FDA's authority at all. So Shane mentioned the 2018 Farm Bill, which descheduled hemp. That Bill expressly retained FDA's authority. And you know there's a bunch of stuff going on at FDA right now around how is FDA going to regulate CBD. You know, the agency's view is look, CBD is not as safe as stuff we normally put in food we need, you know, we don't really want to regulate it as a drug. We need kind of new authority to deal with this product. So

Patti Zettler (she/her): you know, I think it's just important to recognize that wherever wherever things land on the sort of Controlled Substance Act scheduling front, FDA's current statutory authority exists and won't change. I do think it's also important to recognize, and I think we'll talk about this more as we talk about criminal penalties, that although there are criminal penalties under the Federal Food Drug and Cosmetic Act for violating that statute,
Patti Zettler (she/her): they typically in general, do not reach mere possession or mere use. So FDA's authorities are focused on distribution of products or their components in interstate commerce. So typically doesn't reach like a person who happens to be possessing, say, an unapproved drug and using it for themselves, reaches the entity that is distributing that product. So I'll stop there. But that's sort of the the big picture idea.

Cat Packer: Yeah, thanks for for that, Patti. I I definitely will come back to this later. Important to to note the FDA's authority not necessarily changing, but I think folks are eager to know how its position may change if if there are changes to this schedule. But talking about the schedule, I'd like to get specifically back into the CSA and

Cat Packer: talk about the ways in which marijuana status can be changed

Cat Packer: under the Controlled Substances Act. So let's get into the details of the administrative process. First, I'd like to know, is is the administrative process the only way to to make this change? And then what are the details of the administrative process? Who's involved? What factors are folks looking at? Who's the ultimate decision maker? And Shane, I'd like to start with you.

Shane Pennington: Sure. So fair warning, this

Shane Pennington: process is extremely detailed. And so I'm going to hit it at

Shane Pennington: sort of a high level of generality. If people want more detail, or it may come up, I'm happy to, to, you know talk about some of the nuances.

Shane Pennington: But at a high level,

Shane Pennington: the there are 2 ways to change a substance's scheduling status under the current federal law. One is legislation, and sometimes Congress does legislate. For example, the 2018 Farm Bill. Although they didn't technically deschedule, they did change the definition of marijuana, which had the effect
Shane Pennington: of descheduling hemp. So that's that's one way, the other way is, and and they've done it with other substances. They've done it with anabolic steroids. They did a change with GHB. They've done different things so

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Shane Pennington: they can do it that way.

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Shane Pennington: The other way is an administrative process, and it's important to understand when you know some people aren't familiar with how administrative agencies work at all. And those who are familiar are usually, even even lawyers, are usually, you know, when they think of an administrative change, they think of noticing comment, rule, making, or or informal rule making under the Administrative Procedure Act.

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Shane Pennington: That's where an agency posts a proposed rule in the Federal Register, stakeholders and interested persons can comment on the rule. The agency considers those comments, responds to the substantive ones, and issues a final rule which then has the force and effect of law, and is subject to to judicial review.

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Shane Pennington: That process is part of the administrative scheduling

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Shane Pennington: regime under the Controlled Substances Act. But it's just one small part of it. And, in fact, the the process that the CSA calls for is a very rare one

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Shane Pennington: that

00:34:17.889 --> 00:34:38.699
Shane Pennington: as far as I know, I mean, I think it's used in like rate making and maybe a handful of Federal statutes these days. And the CSA is one that's really flown under the radar that most people aren't aware, it actually requires formal on the record rule making. And this process, usually historically, has taken an average of 9.2 years to complete this. And the way that it works, is

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Shane Pennington: the Attorney General whose authority is delegated to DEA or HHS, whose authority has been delegated to FDA,

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Shane Pennington: or so DEA, HHS, or any interested person, may petition DEA to change the scheduling status of a substance or to place of substance on the schedules, and when that happens,

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Shane Pennington: DEA usually just dismisses them without saying anything, and and no one sees it because they either don't accept the petition for filing, or they find it completely unmeritorious, and they sort of just dismiss it out of hand. And and you don't see those. And there are a lot of those I happen to know, because I FOIAed all of them.

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Shane Pennington: But if you get past that first gate, at DEA, then what will happen is DEA will gather the necessary evidence, whatever that means. And it's a little bit unclear, but it will also request the scientific and medical evaluation of HHS, which is FDA,

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Shane Pennington: and HHS's scheduling recommendation, and those that first step in getting that information from HHS is extraordinarily important in the rest of the process, because HHS's scheduling recommendation.

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Shane Pennington: Basically, DEA can't go

00:36:04.540 --> 00:36:13.399
Shane Pennington: more strict than that. And historically it never has is never gone. It has never overruled FDA to go stricter than HHS's recommendation, at least under the 8 11

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Shane Pennington: process. There's a treaty thing that we can get to later, but for purposes of the general process, they they usually take HHS's recommendation.

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Shane Pennington: HHS also sends the scientific and medical evaluation, and DEA. Is bound to accept HHS's scientific and medical findings in that evaluation which is which is extremely important

00:36:39.450 --> 00:36:45.199
Shane Pennington: DEA through the rest of the process. So once DEA has all this information,
Shane Pennington: it then does its own analysis, and this analysis for both agencies.

Shane Pennington: there they must consider 8 factors which are listed in the statute, and they must make 3 findings in order to place a substance in the schedules, and I will go into all the details about what those considerations are, and what those findings are, we can get to that.

Shane Pennington: But once DEA repeats the process, having considered FDA's views,

Shane Pennington: it then proposes a rule in the Federal register, and at the same time it says, Hey, if anybody wants to comment on this, they have 60 days to do so. Also, if you are an interested party,

Shane Pennington: you may request a hearing, and if folks request a hearing, and DEA

Shane Pennington: grants the request, then the hearing is done on the record in front of a DEA administrative law judge, and it has, like trial like procedures with, like, you know.

Shane Pennington: testimony and witnesses and cross-examination. You can put on evidence. You can object to things formally, and the ALJ, like a trial judge, will sit there and

Shane Pennington: look at all that stuff and make up and down findings on it, and issue what are called findings of facts and conclusions of law once all of that is together. So we have the notice and comment which we normally have, plus the ALJ record from any hearings, plus DEA and FDA's analysis, which usually spans somewhere in the range of 50 to 150 pages of

Shane Pennington: you know, Federal Register print,

Shane Pennington: that all goes to the administrator of DAE, who considers it all, and then puts a final rule in the Federal Register, which is then subject to this judicial review under 21 USC 877, in a Federal Appellate Court.
Shane Pennington: And then,

Shane Pennington: once you're done with that, if everybody is still alive and not sleep, you're done.

Cat Packer: Okay? So again, just a little complicated.

Cat Packer: Shane, I'm I'm curious.

Cat Packer: Where, where are we at in this process? Where do we imagine that we're at with this process now with the Biden Administration? And part of the reason why, I ask is, I'm curious to know, like, when will the first official decision be made available to the public? When does the public actually find out any information that's happening with the process?

Shane Pennington: Well, historically, chances are you wouldn't find out anything, usually, because usually DEA does not initiate proceedings. It doesn't think there's substantial evidence, having considered all that stuff to warrant a change in a substance's to schedule or placing a substance on or removing it. So when there's not that substantial evidence, DEA doesn't initiate proceedings. So you don't get a proposed rule, and there's nothing in the Federal Register, and it's a nothing burger, that no one sees right complete black box. Now,

Shane Pennington: the more sort of political salience or public interest there is in a particular scheduling proceedings, sometimes, like in the eighties, for example, and at certain points in the big, the normal, rescheduling

Shane Pennington: Kafka-esque nightmare that took 32 years and spanned the like you know the entire history of the CSA up until 1992, I think,

Shane Pennington: they did kind of open the kimono a little bit and say, you know, FDA would actually put its own analysis out there for public comment, and it would say, here's what we're thinking of recommending, and we would like to have a hearing at FDA before we finalize our recommendation to DEA. So that's happened before. Interestingly, Governor Polis, in Colorado and Senator or who was it, Blumenauer, and several others have actually asked
Shane Pennington: HHS to please open this process up and let us know where things stand, and and let's be transparent and forthright about where where this is going, since it's supposed to be expeditious, etc.

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Shane Pennington: That hasn't happened yet, but, as far as I know, no one has formally petitioned either agency for that request. So it's just been informal letters, which is fine. But if you really want to get some action from one of these administrative agencies in my experience, you need to put your your request formally in front of them and really press it. And no one's done that.

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Shane Pennington: And so if

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Shane Pennington: if we are to see anything, it will be

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Shane Pennington: when DEA eventually, if they do, puts a proposed rule in the Federal Register, and that will be after we have FDA's recommendation, which, of course, it will almost be a fait accompli at that point, right? Because HHS's recommendation

00:41:07.810 --> 00:41:14.840
Shane Pennington: you know, has so much weight in the process, because it's binding on science and medicine, and because it's recommendation is rarely

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Shane Pennington: or I think, never

00:41:17.380 --> 00:41:34.490
Shane Pennington: ignored by DEA. So the only question would be, what is DEA gonna do with the treaties. And so it's just people need to understand that by the time we see something, yeah, you can comment, and you can raise objections, and that can be a very long and drawn out process, and eventually there will be judicial review. But we're already, we've already got a pretty

00:41:34.620 --> 00:41:58.450
Shane Pennington: scrambled and cooked omelet by the time you actually see it for the first time in public, and as far as where we are the scuttle but is that and I mean, I think this came out the other day where Secretary Becerra, actually told, I believe it was Marijuana Moment, Kyle Jaeger said, yeah, we want to have our recommendation in our input over to DEA by the end of this year, which, if that does in fact happen, then

00:41:58.640 --> 00:42:01.810
Shane Pennington: kudos to them because they have moved on an expeditious basis. Because because, historically, that process is taken, I think it's like 2.9 years for HHS to get its input over to DEA on average. And so they're moving at a real fast clip here, if, in fact, they're able to do that.

Cat Packer: Okay, that's that's helpful because I I've been wondering just when when an official decision would be made, and understanding that it seemed as though by the time, if there was a change, you know, it's not like there, there'd be an opportunity for engagement on the FDA's recommendation. We probably won't even see the FDA recommendation until after a rule making processes is initiated. If one is actually initiated. Is is that correct?

Shane Pennington: Yeah and I mean, I tried to get. And I'll try right now. I see there are 212 people here. If anybody wants to request a part C. Part 15 hearing from FDA on this.

Shane Pennington: I think it might be too late. But we could really try to open the process up, and I would love to...

Patti Zettler (she/her): You can just request like an advisory committee hearing which is what FDA did when it recommended up scheduling hydrocodone and combination products to schedule two. But so there are all kinds of public meetings that you can request. They don't have to be so onerous as a part 15 hearing.

Shane Pennington: To Cat's question right? Like, when are we gonna see it, you know. And I think I mean, there might be other ways to get a public hearing or a public meeting like a Town Hall style, whatever.

Shane Pennington: But I just don't know that anyone has has asked, and that's that would be great if anybody wants to do that. Let's do that.
Cat Packer: Yeah, I'm interested. So we'll continue these conversations. But, Patti, I'm I'm interested in getting your feedback on you know, we we talked about the administrative process, Shane shared a lot of information about that just a little bit complicated process. But can you talk to me substantively about what factors the FDA is actually looking at when it's doing its analysis? And

Cat Packer: in relation to those factors, what would it take for, you know, what type of evidence would it take for

Cat Packer: the FDA to to recommend either, you know, rescheduling cannabis or descheduling cannabis?

Patti Zettler (she/her): Yeah, I mean that that's a good question. I I mean, I guess I am mindful of our time, and as Shane mentioned, there are 8 factors in the statute that FDA considers and you know it

Patti Zettler (she/her): cannabis, I guess, is is

Patti Zettler (she/her): somewhat unusually positioned in that there is more widespread use often, and when we're talking about a wholly sort of new substance,

Patti Zettler (she/her): so you know it,

Patti Zettler (she/her): FDA considers those 8 factors. It makes its recommendation to HHS, HHS FDA is situated within the Department of Health and Human services so, as Shane mentioned, it's actually HHS's recommendation. So HHS has to kind of okay, whatever recommendation is coming from FDA before it officially goes to DEA.

Patti Zettler (she/her): I'm not sure I have any, you know, I just I think this is sort of an unusual

Patti Zettler (she/her): political moment with the Administration clearly interested in FDA giving a recommendation, that would
Patti Zettler (she/her): reschedule or do something different with cannabis. Or at least, I think that's what's going on. I defer to others who maybe are following the administration statements more closely. So you know I I

Patti Zettler (she/her): I do think this is an opportunity for a moment for FDA to be a bit more flexible than perhaps it might have been in the past about what kinds of evidence it will consider sufficient.

Patti Zettler (she/her): But I mean I I guess I I think maybe the most important takeaway is is Shane's point about petitioning

Patti Zettler (she/her): the agencies to open up the process in some way. And FDA does have a formal citizen petition process where anybody can submit a petition to the agency, known as a citizen petition. The agency's response to the citizen petition is a final agency action. So the agency can be sued on that response. You know the deadline is, you know, the agency is typically pretty slow in responding to those citizen petitions. But that is one way to do something like request

Patti Zettler (she/her): you know, I think an advisory committee meeting might be a really sensible request here, because, that's a a way for FDA to take its question to outside scientific experts. Those are the Federal Advisory Committee Act also requires that those are all open to the public and FDA posts all the information

Patti Zettler (she/her): publicly that's presented to the Advisory committee meeting, and they typically happen faster than a part 15 meeting. But there are other kinds of public meetings that could be requested. So I'm not sure, like the nitty gritty of what FDA is going to consider internally is

Patti Zettler (she/her): maybe as important as trying to find avenues for public comment, if that's what people are interested in doing.

Cat Packer: And as I understand normally, this term is associated with products, drugs that have gone through the FDA approval process. I'm curious, because whole plant cannabis

Cat Packer: is not FDA approved. How can we get to a point where the the FDA can even consider marijuana to have this accepted medical use based on its kind of historic characterization of of what that accepted medical use is meaning, you know, an FDA approved drug.
Patti Zettler (she/her): Yeah, I'll defer, I guess mothers went away, and I'm curious what others think. But I think from
the FDA perspective, it's actually a pretty tough position for the agency to be in, because for other substances,

Patti Zettler (she/her): you know, for for lots of other things we probably don't want FDA claiming there are currently
accepted medical uses

Patti Zettler (she/her): just because it creates some sort of it creates some tension with the public health value of FDA
gatekeeping for drugs in general and you know I do think it is it is a difficult

Patti Zettler (she/her): statutory interpretation problem, perhaps, for the agency about how it can get to saying there's
a currently accepted medical use for cannabis without undermining its really deeply important public health role in
ensuring that rigorous scientific evidence of safety and effectiveness is created for all the drugs we all use. And you
know that that it can help ensure that products that are

Patti Zettler (she/her): distributed and marketed to us are safe and effective.

Shane Pennington: I'd like to... Go ahead John.

John Hudak: I was just gonna say quickly, Patti, I I really like what you said there, and I think it, it creates what is this
this challenge that exists within administrative law, where

John Hudak: I think a lay person could look at that term and say, Oh, accepted medical use. Well, there's a lot of
doctors who recommend cannabis. They're teaching cannabis pharmacology and cannabis medicine in law schools
and other, I'm sorry, in Med schools and other Allied health programs. So of course, that means there's accepted
medical use. But the the sort of lay version of what that term means, and the way in which an agency interprets what
that

John Hudak: that term means, oftentimes has dramatic differences. And it's not something specific to the Controlled
Substances Act. This happens all across administrative law. And so I think it creates a real frustration within the public
when they look at a standard and say, Well, that's easy. Of of course there's accepted medical use.
John Hudak: Whereas that's much more complicated and much more difficult, as Patti said for FDA in this case.

Shane Pennington: If I could, if I could jump in, and I I, of course, completely agree. And I've litigated the 5 part test the DEA has. So really, DEA said, look at the approval is one way. Obviously, if something has a currently set, if if something is approved for interstate marketing meaning, a Pharma company can profit off of it in interstate commerce as a drug, then certainly that is sufficient

Shane Pennington: to show that it has a currently accepted medical use in treatment in the United States.

Shane Pennington: DEA then said there were a bunch of lawsuits where DEA was unable. Well, courts kept rejecting the argument, that that's the only way. And so DEA created first and 8 part and then a 5 part test that basically mimics the FDA standard. It requires things like repeatable chemistry, which are versus virtually impossible to show with a plant

Shane Pennington: and no matter how much you might want to try. And frankly, nobody's going to do billions of dollars of, you know, clinical trial research on something that there's already a market for across the country, because the only reason that companies put that kind of money into that kind of research is that they can get market exclusivity on the back end and reap the pharma level profits that justify them making the investment in the first place. So really it is a gigantic trap, right? However.

Shane Pennington: FDA has said, and you know I'll just tell you it's a 47 Federal register 28, 1 50. If anybody wants to look it up. And if I could, I just want to read this. I think it's extremely important, alright. This is FDA. And remember, FDA's views are are binding on scientific and medical matters in the scheduling process. And so this is with it. This is in the context of a former marijuana

Shane Pennington: scheduling process, kay.

Shane Pennington: And FDA says, quote, a drug may also theoretically be legally marketed without violating the Federal Food, Drug and Cosmetic Act if it is manufactured, processed, and used entirely within a single State without any connection at all with interstate commerce. The agency has considered whether there is any basis to conclude that the substances at issue in this document have obtained accepted medical use by virtue of totally interstate production and use
Shane Pennington: and has found no basis for a conclusion that these products have obtained acceptance of their medical use by that means. Okay. So now, ultimately there,

Shane Pennington: FDA says, look, it's possible you could do it through entirely through interstate production and use right?

Shane Pennington: It just hasn't happened in 1982. Well, fast forward and you have 38 States sitting here, doctors across the country right?

Shane Pennington: Recommending this to patients in treatment in the United States, and as much as everyone is absolutely correct about the administrative law principles that make it difficult for an agency to change positions,

Shane Pennington: they can. And there's another very important concept of American law called ordinary meaning interpretation. And there are people on the Supreme Court who take that very, very seriously. And so there's something to be said for that instinctive common sense notion

Shane Pennington: that cannabis which is being recommended across the country, and you know, millions of patients are using obviously has a currently accepted medical use and treatment in the United States. And I guess it's unsurprising that if you look hard enough you can find where FDA actually accepted that closer in time to the enactment of the statute which makes a compelling case for them to be able to to sort of say, yeah, we're not remaking the wheel here. We're just saying what we've always said.

Shane Pennington: The only thing that's changed is that now cannabis, unlike any other substance, has, in fact, achieved this status.

Cat Packer: Thanks, Shane. I'd like to jump now to another topic that seems to potentially be limiting on on this conversation around rescheduling or descheduling. As I've been looking at the the process and some of its limitations, what's constantly come up is the international treaties in the US's obligations under the international treaties.
Cat Packer: And so part of what I want to be able to better understand is, do US treaty obligations limit the Federal Government's ability to deschedule marijuana within the administrative process that's happening right now? And then I'm also curious in folks response to the the DEA opinion in 2016 where they articulated that because of the the obligations under the international treaties marijuana couldn't be placed in a schedule less restrictive than schedule one or schedule 2. So can folks talk a little bit about the implications of the treaties, and I want to start with Fatima.

Fatima Afia: Sure. So as you pointed out under the CSA, 21 US Code 8, 11, D1. I'm gonna just read it verbatim. The CSA provides that if control is required by US 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 that are required under either this section or 8 12 B of this title, which includes all the different schedules and the criteria for those schedules.

Fatima Afia: So, yes, essentially, based on the language of the CSA, and this is how the DEA has also interpreted its own authority. We are bound, or federal, the Federal Government is bound by its own treaty obligations, and so, because the United States is a member of the single convention on narcotics, among other treaties, that was established in 1961,

Fatima Afia: we do have to to some extent make sure that any scheduling of cannabis, or any other drug is consistent with how those drugs are being scheduled under those treaties. So in, as you mentioned, in 2016 the DEA in the I think it was the the latest rescheduling petition for cannabis that was ever filed with the DEA. In that decision on that rescheduling petition they did take the position they couldn't reschedule anything below a schedule two in order to stay consistent with the obligations in for the single commission on narcotics. Interestingly, though in December of 2020, I believe the UN did, WHO actually, I believe.
Fatima Afia: reclassified cannabis under the single convention on narcotics. I don't know. I don't recall exactly which schedule they replaced it to, but I believe they removed it from schedule 4 under the single convention, and they

acknowledged that there are medical efficacies and therapeutic uses for cannabis. So theoretically, there is a lot of debate with everyone I talked to as to what kind of as to what schedule under the CSA. That would mean we could actually reclassify. But I've been hearing rumbles of either a schedule two, as the DEA has previously said, or perhaps maybe now a schedule 3. Since schedule 3 does acknowledge that there is medical use and less of a psychological physical dependence. So

Fatima Afia: that's sort of how we get there. I am interested in hearing Shane's view on sort of more the nuances of the treaty schedules, because I don't know all the schedules by heart. But my understanding, though, is that DEA has always taken this position, and it's pretty clear in the CSA that they don't really have much of a choice there

Cat Packer: Before before you jump in Shane, Rob is, do you have anything that you'd like to to comment on this particular piece?

Robert Mikos: I think, Fatima did a a good job of sort of summarizing the obstacle here. And the key is to to recognize that at least as a matter of administrative scheduling power, Congress has pretty much tied the hands of the DEA and HHS and the Attorney General to the math of international law. So if international law requires the United States to control marijuana in a particular way, the administrative branch has has no choice but to heed those obligations, and I think that the most straightforward, back to the the ordinary meaning of the International conventions, the way that the International Narcotics Control Board has interpreted them, that would probably require the United States to keep marijuana, at least on schedule 2, to not relax the controls any more than that.

Robert Mikos: But 1 one thing I'll add to this is that this only applies to

Robert Mikos: the Executive branch. If Congress wants to, Congress can can pass the statute saying
Robert Mikos: we don't care at all about international law, and and Congress could create an exemption for marijuana on descheduling it entirely in the same way it did.

Robert Mikos: tobacco and alcohol and hemp or just saying sort of legislatively, we're going to move cannabis or marijuana to schedule 3, schedules four schedule 5 or some new schedule. So this is really only a constraint on the President's power. It's not a constraint at all on Congress.

Fatima Afia: And to add to that, it's also clearly not a constraint on State powers, because, as we've seen, multiple states more and more every day are legalizing. The UN has called the United States out on this saying that by allowing States to continue legalizing in flagrant violation of not only us Federal law, but of also the international treaties that we are already actually in violation of their our treaty obligations. So there's that.

Shane Pennington: And if I could just jump in real quick. So,

Shane Pennington: not only are we in violation of the treaties, we're going to be in violation of the treaties, regardless of the outcome of this administrative process. You know, schedule 1, 2, 3, 4, 5 deschedule, we're going to be in violation because of the State legal markets. The CND is repeatedly said that year after year after year, and beyond that, something many people don't realize is that this is part of a a lawsuit that one of the lawsuits, the end of the NIDA monopoly, we actually get

Shane Pennington: found through a complex FOIA process, the office of legal counsel, which is a very high authority in the executive branch, actually found it from the beginning of DEA's existence in 1973 the United States has been out of compliance with its treaty obligations in 3 ways because of the NIDA monopoly which blocks scientific research in the United States for 50 years.

Shane Pennington: And so we've never complied with the treaties. We're not complying now, and we're not going to be complying unless we address our deeper relationship to those obligations.

Shane Pennington: And I guess that you know another thing that has to be said. I just published a a law review article about this with Matt Zorn where we explain that, you know, because of the Federalism implications of, you know, trying to enforce a treaty that would require us to require the Federal Government to go in and sort of stop the state level programs
Shane Pennington: and also because of the private non delegation doctrine, the treaty obligations under 8 11 D are very likely unconstitutional. And so the treaty as a self executing soc is not a self executing document, which means there has to be a federal law that implements it as a matter of domestic law, and if that domestic law, section 8, 11 D of the CSA. Is itself unconstitutional, that it's invalid. And so that would be another way for the agency to get around that.

Shane Pennington: And right now, I'm working on a petition that is, teeing up that so that basically they will know that if they try to apply the treaties to keep cannabis in any particular schedule that we'll be challenging the constitutionality of 8 11 d.

John Hudak: I think, also like to strip away the the legal and constitutional complexities of this, and we just look at the international politics of it.

John Hudak: Uruguay wasn't sanctioned for legalizing cannabis in 2013, I mean, yeah, and Canada later. I mean the the UN wagged their finger at Uruguay really, really angrily. But if Uruguay is not going to face sanctions from the international community about legalizing, I can guarantee you the United States will not.

John Hudak: And and, as Fatima said, like Canada a a a pure country economically also got a really aggressive finger wagging. But nothing's coming of it.

Fatima Afia: Did Mexico even get a singer wagging?

John Hudak: I don't even think they did. And so so the the international politics there really, don't

John Hudak: create any barrier for the United States to essentially do whatever the hell it wants. There might be domestic limitations. There, there, maybe not with with Shane said, but internationally.

John Hudak: You know, it's it's not going to be, it's it's only going to be a little speed bump.
Cat Packer: Alright. Well, I I appreciate all of that context. I feel like I have a much better understanding of the process itself, and I'd like to shift our conversation now and talk about some of the implications of potentially rescheduling or descheduling.

Cat Packer: cannabis. Before we get into this conversation, I'd like to try and frame this conversation with 3 thoughts generally.

Cat Packer: First and foremost, I recognize that there are many different stakeholders and issues that are impacted by marijuana status under Federal law.

Cat Packer: And I want to make sure I have a better understanding of what changes impact whom and how certain changes may leave certain State stakeholders and issues without adequate relief.

Cat Packer: I've in my exploration of these issues identified several areas of law that I think are worth considering when trying to understand the implications of changing marijuana status under Federal law. And I've put together a chart that I hope to be able to share with folks and get feedback on that that walks through that but beyond

Cat Packer: my personal consideration of what I think are important issues to consider, I also like us to have a conversation in part about where the Biden Administration has said that they stand on marijuana

Cat Packer: and what

Cat Packer: particular schedule, deschedule would be necessary to accomplish and effectuate those goals. I would also like to just note

Cat Packer: that it seems as though at least, according to a cannabis journalist, John Schroyer that there's some chatter that the Biden Administration may move to schedule 3. And so I think at least

Cat Packer: while I don't want to be speculative on the the call, I think it's at least helpful to use this as a hypothetical as we go through these different issues. I'm going to ask the panelists to be able to comment specifically in a hypothetical situation. If we were to be rescheduled to schedule 3, what those particular implications
Cat Packer: would mean? Does that all make sense to panelists? And and work for folks?

Cat Packer: Excellent. Okay. And folks can still see my screen?

Cat Packer: Let's see if we can still do this. Okay. So

Cat Packer: I put some time putting together this chart to try and understand some of the legal implications of marijuana status as a controlled substance. And just so folks know I I will be working with Ohio State University and the Drug Policy Alliance to publish this resource following this conversation after I have an opportunity to get feedback from our experts today.

Cat Packer: But I'm hoping to be able to use what I put together for discussion purposes only. Please don't take this to the bank, this is not legal advice. But I'm hoping this can at least help us frame some of the different conversations and and what I've tried to do here is categorize by legal status, by schedule or considering whether or not marijuana would be descheduled.

Cat Packer: or address through legislation what the particular implications could be. So we'll go one by one through these different issues and I'd like to start by talking about some some of the research. But let me let me back up for a second, because I I recognize I did not add a key to to this illustration, and so let me just try and articulate what some of these symbols mean. The yellow circles with X's are intended to represent a situation status where that activity is technically legally permissible, but highly regulated, the red circles with the X means that it either is not addressed through that particular status of law, and the green circles with the check represent either

Cat Packer: law being able to to address those particular issues, or those things still being
Cat Packer: permissible under under

01:07:37.670 --> 01:07:47.729
Cat Packer: whatever particular status. So I’d like to start with research and I want to have a better understanding of how either rescheduling, descheduling

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Cat Packer: to keep with our example, moving specifically to schedule 3 would impact marijuana related research. And part of what I want to ask is how the research bill that President Biden signed last year, how that is factoring into how research could be changed if

01:08:09.070 --> 01:08:14.060
Cat Packer: marijuana was rescheduled or descheduled, and I’d like to pass that question to Shane.

01:08:15.320 --> 01:08:21.999
Shane Pennington: Thanks. Yeah. So research is kind of near and dear to my heart. It’s part of the reason I got involved in in this area of wall to begin with.

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Shane Pennington: And so before that, the President signed the Marijuana and Cannabinoid Research Expansion Act, and I think it was December 2022 could have been November, but sometime

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Shane Pennington: around there. Before then the way that it worked was, you know, the Controlled Substances Act

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Shane Pennington: made research more or less difficult, based on the class or scheduling status of a substance. So schedule one substances had extremely restrictive

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Shane Pennington: research requirements imposed on them, like basically make made it, you know,

01:08:55.520 --> 01:09:15.450
Shane Pennington: not impossible, but very difficult to do any serious scientific study of the cannabis, especially cannabis people are like actually using in the United States. And then for other schedules, it was less strict, you know. So schedule 2 was little bit less strict, and then for 3, 3, 5, it was significantly less strict.

01:09:15.800 --> 01:09:21.080
Shane Pennington: The the statute that was passed at the end of last year, however,
Shane Pennington: change that approach

Shane Pennington: and addressed cannabis itself specifically. So it says, for purposes of

Shane Pennington: marijuana research, here are the standards right? And so, instead of saying, as long as cannabis is in schedule one, these are the standards that apply it just says, these are the standards that apply to Cannabis period. And the trouble with that, I'm afraid. And you know I'm the only person who's

Shane Pennington: got this fear, I think. But nevertheless, I'm concerned that because the statute now singles out cannabis for very particular and strict requirements, regardless of its scheduling status, the only way we're going to get serious relaxation of the research requirements is if we get all the way to descheduling. Now, hopefully, if I'm my fear is true, right? I mean hopefully, I'm wrong. Okay. But if I'm correct, my hope would be that okay, well, if they rescheduled, say to Schedule 3, and you know the research strictures that applied when cannabis was in schedule, one still applied because of this recently enacted amendment,

Shane Pennington: that Congress would step in quickly and relax those requirements.

Shane Pennington: But it would just be very unfortunate. I think most people very reasonably think, Oh, well, if we reschedule, that's going to really help scientific research, I mean, that's what I thought until this statute was passed. So that's my fear. If it is like the other schedules, though, Schedule 3, you know, if it

Shane Pennington: aside from that concern in general schedule 3 has a lot less research restrictions than schedule one. So that would be a a major boost for the scientific study of cannabis.
Cat Packer: Thank you, Shane. I'd like to move on to and I'm not necessarily going in an order of what's on the screen. But I'd like to shift into talking about one of the things that we raised earlier, which is this concept of accepted medical use.

Cat Packer: And as I understand, one of the major distinctions, if we even just move out of schedule, one to any other schedule or deschedule part of this acknowledgment would be in. I think, John, you were referring to how the agency views accepted medical use. Patti I'm interested in understanding what what the significance and practical impact of this designation accepted medical use is. And whether or not this impacts how FDA would go about approving a marijuana drug.

Cat Packer: We'll start there.

Patti Zettler (she/her): Yeah. So I mean in just to, I guess add to what Shane said about research. It is research with human subjects is highly regulated, even for totally deep for substances that aren't in aren't scheduled under the Controlled Substances Act. So there's a there's a regulatory regime in place to ensure that human subjects welfare is protected and ensure that studies are designed in a way that's valid scientifically. So we actually get information about safety and effectiveness that would apply in many instances, regardless of whether cannabis is scheduled or not. Both under the Federal Food Drug and Cosmetic Act and under a separate something know as the common rule, which is a regulation under HHS, not under FDA. bBut in terms of accepted medical use, it really doesn't have any bearing on FDA approval status. So you know

Patti Zettler (she/her): apply

Patti Zettler (she/her): in many instances, regardless of whether cannabis is scheduled or not. Both under the Federal Food Drug and Cosmetic Act and under a separate something know as the common rule, which is a regulation under HHS, not under FDA. bBut in terms of accepted medical use, it really doesn't have any bearing on FDA approval status. So you know

Patti Zettler (she/her): I think, as Shane mentioned, typically when FDA has said something has accepted medical use, the product has gone through the FDA approval process.

Patti Zettler (she/her): I mean, I think it'll be interesting to see what FDA says during this kind of rescheduling scenario, where perhaps it will find an accepted medical use absent and FDA approval. But the
Patti Zettler (she/her): FDA approval process and at the statutory requirement for FDA approval remains in place regardless of the schedule that a drug is on, or whether it a drug is not on the schedule at all. You know, I will say the one

Patti Zettler (she/her): sort of nuance there to FDA's authority that might be important here is sort of returning to the Federal Register Notice Shane mentioned where FDA talked about wholly intrastate production, so FDA's authority by statute is tied to the movement of a product or one of its components in interstate commerce. So a wholly intra state business, where a product, all parts of the product are sourced from within one state, distribution is fully within one state

Patti Zettler (she/her): etc. that

Patti Zettler (she/her): might not be something that would require FDA approval, simply because FDA does not have statutory authority over wholly intrastate business.

Cat Packer: Thanks, Patti. I think one of the things I'm interested in in getting a better understanding of, particularly around medical and medical use and and FDA drug approval is trying to reconcile like, what does this actually mean for patients? If cannabis is, if marijuana is rescheduled, does this automatically address, you know, medical use as authorized by a state law? Does it mean that we're talking prescription access? What are we, what are we talking about here? And Patti, if you can comment and I'd also be interested in follow up from Rob.

Patti Zettler (she/her): Yeah, I mean. So I think that's a great question. I know folks in the Q and A had had written questions about payment. Would we expect payers to pay if marijuana or caretaker cannabis were on a lower schedule and an FDA made a termination that accepted medical use. And what about FDA enforcement? So I I mean, I think it's a big looming question would be. I've been talking about what FDA's statutory authority is
Patti Zettler (she/her): but you know we can think, I think, as Rob mentioned at the outset, right, law is not just what's on the books, it's how it's been forced, and you know, to we think FDA would have an appetite for enforcing

Patti Zettler (she/her): you know, some of these existing medical uses, and you know, there, I think it's it's a bit hard to predict. And it's probably product specific. And you know, the agency typically makes enforcement decisions on kind of a case by case basis thinking about you know where the public health risks are and what the best use of this resources are. But you know, I think in terms of patient access it's

Patti Zettler (she/her): I'm not sure it will have a big impact. I you know I don't know that I would expect insurance companies to start paying just because cannabis is on a lower schedule, absent FDA approval.

Patti Zettler (she/her): But you know, maybe I'm wrong about that.

Cat Packer: Thanks, Patti. Rob?

Robert Mikos: Yeah, I I think it's important to keep in mind that even if

Robert Mikos: the Federal Government were to move marijuana down to schedule 2 or schedule 3, that would trigger a a new set of regulation on both those under the Food Drug and Cosmetic Act, as Patti mentioned, but also under the CSA.

Robert Mikos: There are lots of rules governing how companies are supposed to handle and produce these substances, how individuals are supposed to get access to them, and so on. And and usually it is, if it's a schedule 2 or schedule 3 substance, usually it is

Robert Mikos: more of a prescription rather than just a doctor's recommendation. So all that's to say that there there would still be a gap between current State medical marijuana laws and the regulations that would exist under Federal law. But if States could could somehow close that gap, if they could find a way to to reformulate their regulations so
Robert Mikos: actions that are in compliance with state, medical marijuana laws were also in compliance with Federal laws pertaining to say, a schedule 3 substance, then, yeah, I think you would have a big impact. You could have individuals lawfully possessing this substance, you would have insurance companies, as long as there’s a scientific backing for it.

Robert Mikos: covering the cost of medical marijuana, which is something they haven’t done in the past. You would have employment protections kick in under the Americans with Disabilities Act for example. But that would require some work. It wouldn’t happen automatically, because there’s still a gap between state medical marijuana laws and federal laws govern these substances.

Robert Mikos: The other thing to keep in mind here is that it would have no impact whatsoever on adult use. So under Federal law, really, it’s a medicalized view of the world. So if you’ve got a controlled substance, even if it’s a controlled substance on schedule 2, 3, 4, 5, the only valid use for that is for medical. There’s no other valid use. So it wouldn’t really have any impact at all on adult use laws. But it could potentially down the road, have an impact on medical marijuana laws.

Cat Packer: Thanks for that, Rob. And I guess part of the clarification even around the impact it could have on on

Cat Packer: medical marijuana laws, I’m imagining because we’re still talking, we’re still talking about rescheduling cannabis we’re still talking about the DEA’s closed loop system where folks who were producing, manufacturing, distributing medical cannabis would still have to get a license from the DEA correct? Is that correct Rob?

Robert Mikos: That’s correct. And just to drive the point home, consider that cocaine is a schedule two controlled substance.

Robert Mikos: And yet, I bet you wouldn’t walk down to your neighborhood Walgreens, and say, Hey, my doctor just wrote me a prescription for cocaine. Can I kind of get my drug here? That drug because it’s on schedule 2. It’s subject to a litany of controls that go far beyond
Robert Mikos: anything the States, any State has imposed on medical marijuana. So yeah, there there would be hoops to jump through. There would be licenses you’d need to get. There would be protocols you’d need to follow new regulations and so on

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Robert Mikos: that it would make it restrictive, but you you open that door a crack, and and there are some people I think it at least would benefit from that. And again, if States gonna change, their laws become more restrictive, more in line with with Federal regulations, you have might have more and more people benefit down the road.

01:20:14.690 --> 01:20:27.719

Cat Packer: Got it? Thank you. I think I think all of that clarification is really helpful, because I've I've seen chatter on social media. And it seems like there's there's at least some belief that rescheduling would just, you know,

01:20:27.720 --> 01:20:45.149

Cat Packer: automatically legalize medical uses as it's situated at the the Federal level or that the operators who are participating in in medical industry across the United States would would somehow be brought in in. In reality, it seems like

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Cat Packer: there there's a window that could open. And it's whether or not folks could contort to to fit through that window and and then on the back end

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Cat Packer: it's kind of every individual product may need to be approved in order for folks to get, for example, prescription access to that particular product. So seems like, this is another one of these areas where it may be, just a little bit complicated, but I do appreciate folks being able to give clear responses and and clarify. No, this is not going to in any way address

01:21:19.170 --> 01:21:25.570

Cat Packer: you know, adult use programs or medical use.

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Cat Packer: Rob, I'm I'm sorry, John. I'm I'm specifically interested in your feedback as a current regulator. What do you anticipate any of this descheduling, rescheduling, moving to schedule 3 to mean for State programs and markets?

01:21:45.830 --> 01:21:58.150

John Hudak: Yeah, thanks, Cat. Descheduling would be a game changer for any of the state programs as they exist, particularly the adult use programs as they exist. I'm still

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John Hudak: not convinced that descheduling would dramatically change the way that the Federal Government used cannabis as a medicine. I I take Rob's point that you could imagine, under a rescheduling or even under a descheduling process, rules being written in ways that could treat cannabis in a way that we perhaps are not thinking about it right now. But

John Hudak: but I I would tend to disagree. I think it's hard to imagine a scenario in which FDA writes

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John Hudak: even slightly permissive rules around medical cannabis that would encourage insurance companies to start reimbursing for it. Just the

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John Hudak: vast differences that States have in the way in which they regulate medical cannabis, I agree with Rob, you could imagine a federal structure that says, well, if you produce cannabis in this way, then perhaps we'll think of it differently. But in reality we have that already, we have a scheduling system in which

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John Hudak: companies can bring cannabis related products to market. It just goes through a rigorous testing and and trial process. And so I think there's a lot of false hope

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John Hudak: in the cannabis industry and among cannabis patients about what rescheduling would mean. But as a State regulator rescheduling doesn't change my job at all. I'm running a system that's illegal under Federal law. Every license in the State of Maine is currently breaking Federal law every day with what they do, and rescheduling from 2 to 3 or 4 or 5

John Hudak: doesn't change that at all. And so

01:23:39.330 --> 01:24:03.050
John Hudak: and and 1 one last note particularly on what might change in terms of accepted medical use or or changes to medical cannabis programs, one of the things that I cannot imagine seeing in the future is in a is a scenario in which FDA produces any type of rule that would ok smoked cannabis flower

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John Hudak: as an accepted medical product. This is the vast majority of medical cannabis in the United States is used to smoked flower and it I would be shocked to see like I said FDA, signing off on that. Tinctures, edibles patches other types of products, perhaps. And we've obviously seen

John Hudak: Epidialex being approved as a pharmaceutical but not smoked cannabis, and there would be profound resistance within the medical community, both inside and outside of FDA to accept that as having medical cannabis use in a state program in any part of the country given the views that exist in the medical community about smoking in general.

Cat Packer: Thanks for that, John. Fatima, did you want some to add something?

Fatima Afia: I just wanted to say that I largely agree with everything that has been said, and particularly with what John is just saying. And I actually, there's been a lot of discussion among a lot of medical advocates in the space that there should perhaps maybe even be

Fatima Afia: not rescheduling to the current set schedules, but actually creating a totally new schedule, 6, which would require legislation, but creating a whole new schedule to really hone down on regulations that actually make sense and practice for this product, which is obviously unique in a number of ways from any of the other pharmaceutical drugs that are currently listed under the CSA.

Fatima Afia: And so there is, you know, a lot of you know push for this. Don't know how likely it is to actually get through into legislation, but it is something worthwhile discussing and thinking about, because, as John alluded to, you know, smoking, perhaps, might be something that would be completely, under the existing schedules, be completely prohibited by the FDA. But if there's legislation

Fatima Afia: that actually creates a totally new framework for how we regulate medical cannabis differently from the other scheduled drugs, that could be a way to sort of transition ourselves into a federally legal industry.

Cat Packer: Yeah, thanks for that Fatima. I think that there will we will there will continue to be conversations about one whether or not the CSA is like the appropriate regulatory apparatus to deal with cannabis at all. And then, of course, there's a conversation about how we're kind of delineating medical and adult use, and and whether or not that's appropriate. As was mentioned previously, the CSA is

Cat Packer: is really only meant to deal with research and and medical purposes, and the reality is that while while I have colleagues who say, like, all cannabis is medicinal, and I, I I agree with that, it's not taking a stock of how States are making these distinctions. And if we are going to make this distinction at the State level, maybe maybe it's time
Cat Packer: that the CSA is just not the appropriate vehicle to do that. I do want to shift and talk specifically about impacts. We talked about how rescheduling wouldn't necessarily address a patient immediately address patients, definitely wouldn't address adult use consumers or state programs, industry authorized by state programs. I do want to spend a little bit more time talking about the cannabis industry.

Cat Packer: One of the areas that it seems like there would be kind of clear cut relief is on the topic of taxation. And so I'd like to have Fatimina, if you can share a little bit more about how rescheduling or descheduling, you know, moving to schedule 3 would impact the ability for the marijuana industry to make tax deductions?

Fatima Afia: So currently, under 280E of the internal revenue code, businesses cannot take ordinary business deductions like most other industry businesses can, if they are engaging in the trafficking of illicit substances, controlled substances, in violation Federal law. So any businesses that are currently operating in violation of schedule one of the Control Substances Act are unable to avail themselves of the normal and ordinary business deductions that many businesses take which really does leave a lot of these businesses in a financial hold. You know, we're already in a very volatile, highly regulated,

Fatima Afia: highly expensive industry, and to top it all off, you now don't even get these ordinary business expenses. So I actually am going to leave it to the rest of my esteemed panelists to talk about the implications of other schedules, because I truly don't know how other schedules will impact to 280E exposure and liability. But I'm interested in hearing everyone else's thoughts on that.

Cat Packer: Yeah, thanks. So in my understanding, it's specifically applicable to schedule one and schedule 2 substances. But if marijuana was moved to schedule 3, 4, 5, or descheduled then cannabis businesses would be able to make that normal business deduction, and I see Shane had put his thumbs up so I'll take that as law. But I think part part of what I think, what I've seen on

Cat Packer: on, on Twitter and social media, And maybe folks can just clarify, I've seen someone ask the question, well, is it, is it just, if it moves to schedule 3, does it just protect the medical portion of the program? And Shane is shaking his head no. Any, any category of of activity if it's scheduled 3 and it
Cat Packer: wouldn't even necessarily, I know, ask the clarifying question. It doesn't even make a distinction about whether or not this is a licensed business at the State level or not. Any one engaged in cannabis activity, if it were moved to schedule 3, 4, 5, or lower would be able to make those normal business deductions.

Shane Pennington: Yes, and if I could just add one point that I think, is almost universally overlooked. And admittedly it's a minor point. But when you're out in the desert, and you're awfully thirsty,

Shane Pennington: you know, a drop of rain is a welcome thing, and so it's worth noting that there's not just 26 US C 280E, there's also 26 US C 7201 which says that the IRS can enforce these tax provisions with criminal penalties. It's a felony punishable by prison time. It fines up to $100,000 for you to try to evade tax requirements, right? And so 280E has criminal implications, and those criminal implications have, you know.

Shane Pennington: criminal justice implications, just like any other criminal penalty. And so to say, that rescheduling, you know, has no criminal justice implications is just technically inaccurate. And it's also important to emphasize that as you deschedule, you know a lot of what's going on at the at the Federal level and at the State level when it comes to the criminal side of enforcement, those are a lot of discretionary decisions that prosecutors and and administrations make.

Shane Pennington: And I think that that's a two way street. So like right now a lot, there's what many of those entities are not exercising that discretion vigorously. Right? We don't see them pouncing all over. Now, that's not to say that the criminal prohibition doesn't have an effect. It certainly does. However, you know, as you move down, as you move to less and less strict schedules along the rescheduling continuum, there's at least some

Shane Pennington: notion that perhaps sentencing judges prosecutors might take that into consideration when they're making the discretionary choices about whether to bring charges and how to sentence if charges are brought, and the last thing I'll say on this, which is another point that I think you know it's just kind of lost in the shuffle,

Shane Pennington: is when you have a really dramatic change like, say, a really revolutionary change like descheduling right? Now, I support personally descheduling vigorously, and I think it's the best outcome. And I and I hope you know we get there sooner rather than later. That said

Shane Pennington: one thing I would be concerned about, you know, if you got descheduling is that we get, you know, sort of the pendulum or reactionary
Shane Pennington: pouncing on that by, you know, the enemies of cannabis reform. Right? So you could imagine states that are prohibitionist states, or an administration that is, that opposes cannabis reform saying, this descheduling is a bridge too far. And now we're going to tighten up all of these discretionary enforcement decisions that we normally haven't done right, and the penalty and could swing back the other way. And that could be an unintended consequence. I'm not saying it would happen.

Shane Pennington: I'm just saying that has happened in areas like immigration law when there have been changes of administration, and because so much is done at the state level. You know, we need to think about how different

Shane Pennington: there, you know, it is more complicated than just to look at the black letter of what the schedules do, and to ignore the political valence and the discretionary power that certain officers have when enforcing the law or not.

Cat Packer: Yeah, I I appreciate

Cat Packer: framing what is a legal, or at least a practical possibility with the schedule change. I I want to at least be able to respond and say, I, I assume that if if judges are going to use discretion later, they could probably use that same discretion now.

Cat Packer: I I agree and I understand that there are criminal penalties associated with the the tax code. I do wanna we can shift now into talking about the the criminal penalties we can come back to the the the banking issue. But let's spend some time talking about the the criminal penalties because

Cat Packer: I've seen folks

Cat Packer: on social media talking about some of the implications of rescheduling or descheduling cannabis and some folks offering in part Shane what what you offered and that there there could be some reduction in penalty if cannabis were rescheduled. But, as I understand, there are cannabis specific

Cat Packer: penalties and so the reality is is that it wouldn't matter if we rescheduled to one to 3 to 5, those cannabis-specific penalties would remain the same. And so I think we have to
Cat Packer: approach these conversations about and a speculative possibilities about criminal justice reform with caution. I think we can talk about them as possibilities, but I wouldn’t want to sell them as absolute.

Cat Packer: because I don't know that we can say that that's the the case.

Cat Packer: John, can you talk a little bit more about

Cat Packer: how cannabis related, marijuana related penalties at the Federal level could change if marijuana were rescheduled, descheduled, and then if you have any specific comments on our hypothetical of schedule 3.

John Hudak: So in terms of the rescheduling of cannabis, it it maintains all of the same criminal penalties that exist. If you're purchasing from illicit avenues, or even frankly purchasing from State legal entities which would remain illegal

John Hudak: under Federal law with with cannabis rescheduled. It also it, even if we get into a a position where legislation happens, where Congress takes the step of removing cannabis from the Controlled Substances Act,

John Hudak: we, it's still unclear what types of penalties the Federal Government would maintain for certain behaviors. So if you look at what States have done, no State has removed

John Hudak: all criminal penalties for all activity related to cannabis. I mean, there are State legal, there are states that have legalized cannabis that you can still get a life sentence for trafficking large amounts of illegally grown cannabis in it. And so the Federal Government will likely also maintain some sort of criminal justice system or criminal justice process for large scale illicit trafficking of cannabis, I would guess. And so

John Hudak: all that said, I'll also note the vast majority of interactions individuals have with the criminal justice system related to cannabis happen at the state level,
John Hudak: the state and local levels. And so even the removal of a simple possession, as a federal crime is going to have such a miniscule impact on criminal justice in the United States and and removing cannabis from the Federal schedules

01:37:13.740 --> 01:37:32.909

John Hudak: also does not strip a state of the ability to maintain cannabis as an illegal substance. And so it doesn't necessarily force the hand of of Rob's home state, my former home State of Tennessee, from maintaining the criminal code with respect to cannabis. And so in a lot of ways, the

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John Hudak: the process that we have seen the progress we've seen in this country over the past 25 years, and particularly with regard to adult use cannabis over the past 11 years. That is the big step

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John Hudak: in terms of addressing criminal justice issues, because so many such a high percentage of arrests that end up becoming exempt happen at the state level, and the steps that governors and legislatures have taken and other institutions have taken to right those wrongs of the past and offer clemency to past offenders. That's the big criminal justice game changer in this country, not

01:38:09.910 --> 01:38:17.389

John Hudak: you know the Attorney General ultimately rescheduling or descheduling cannabis, or even necessarily Congress stepping in.

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Cat Packer: Thanks, John. Patti, I know that you spent some time earlier talking about penalties that could be applicable through the Food and Drug Cosmetic Act. Can you just to tie these conversations together, can you articulate

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Cat Packer: what those penalties are, and and whether or not rescheduling, descheduling would change those penalties, what they what those particular penalties, what activities those penalties are for?

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Patti Zettler (she/her): Sure. So violations of the Federal Food Drug and Cosmetic Act can lead to Federal criminal penalties, Federal criminal prosecution. And in the past, FDA statute has been used to prosecute

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Patti Zettler (she/her): people who are distributing

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Patti Zettler (she/her): drugs for adult use that are not scheduled. But 

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Patti Zettler (she/her): as I mentioned at the outset, FDA statute is really focused on the interstate distribution of products. So a product or its components has to cross state lines or cross, you know, national boundaries at some point generally for FDA to have jurisdiction. So it wouldn't criminalize

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Patti Zettler (she/her): mere possession or personal use. But it, but there would be criminal penalties available potentially, for I think, certainly for interstate

01:39:45.970 --> 01:39:53.389
Patti Zettler (she/her): distribution for medical uses. But the definition of a drug and FDA statute covers articles intended to treat, prevent,

01:39:53.460 --> 01:40:03.110
Patti Zettler (she/her): cure, mitigate disease, etc., or articles intended to affect the structure or function of the body. And it's that second piece of the drug definition that's broad enough to cover adult or recreational use.

01:40:03.140 --> 01:40:26.750
Patti Zettler (she/her): You know, again, as I already mentioned, and, as Rob mentioned, right depends on appetite for enforcement. FDA, like many agencies does not have independent litigation authority. So all of its litigation, whether criminal or civil, goes through the Department of Justice. So it depends on the Department of Justice's appetite for enforcement. But there are those, there are criminal penalties available under FDA statute.

01:40:28.060 --> 01:40:44.639
Cat Packer: Thanks, Patti. I want to shift back to talking just briefly about some of the industry impacts and part of what I have represented here on this chart is marijuana industry banking.

01:40:44.640 --> 01:41:03.040
Cat Packer: And I'll just note my thoughts and folks can kind of correct me if I'm wrong. But my understanding is that rescheduling cannabis, moving it among, on the schedule is, is probably not going to have, and won't have a legal impact on

01:41:04.220 --> 01:41:28.209
Cat Packer: individuals access to marijuana banking. And that's in in part because the underlying commercial cannabis activity would still be considered illegal under Federal law. As folks probably know there there is a a bill in Congress, the SAFE Banking Act that would address this specifically by protecting financial institutions for

01:41:28.400 --> 01:41:58.389
Cat Packer: from Federal enforcement for servicing the cannabis industry. And so, if if the SAFE Banking Act passes, then you know, Banks wouldn't be subject to to that potential enforcement. However, if cannabis were completely descheduled, then the SAFE Baking act itself would be moot. There, there would be no need for it. Does anyone else have any commentary on potential impacts to banking?

01:41:59.360 --> 01:42:23.739
Cat Packer: All right. I'll shift. I want to be able to close out our our conversation on the implications, talking about how the DEA and FDA authority could change if cannabis is either rescheduled or descheduled, so Shane can you talk a little bit about what would change if cannabis was rescheduled or descheduled in terms of da authority?

01:42:24.850 --> 01:42:37.040
Shane Pennington: So yeah, sure. So DEA shares authority with FDA over controlled substances, I mean, Patti's gone over the FDA's authority. FDA is authority doesn't change

01:42:37.060 --> 01:42:55.849
Shane Pennington: by and large when a substance is descheduled, it's still subject to all of the interstate marketing constraints and the false advertising, labeling requirements, and so forth when marketed in interstate commerce, regardless of scheduling. So that wouldn't change. DEA's authority

01:42:55.880 --> 01:43:13.510
Shane Pennington: does change. So in order for da to have jurisdiction or authority over a substance under the Controlled Substances Act, that substance has to be on one of the schedules, and that means that the Attorney General has to have made the findings in 21 USC 8 12 relevant to

01:43:13.570 --> 01:43:22.990
Shane Pennington: placing it on one of those schedules. And so, if it's descheduled, DEA doesn't have authority over it much like hemp as an example, right? When the 2018 Farm Bill came out

01:43:23.040 --> 01:43:33.030
Shane Pennington: FDA's authority remained. DEA was out of the ball game with respect to hemp. Now, it's important to make one other point here, and that is that

01:43:33.110 --> 01:43:57.980
Shane Pennington: you know, if you're FDA, right, and you think about the amount of resources it would take to like really strictly enforce the FDCA on against the State level cannabis markets. And you think about the fact that FDA is a unique agency in the sense that a whole bunch of it's money comes from farmer company user fees and it doesn't have any you know, it's not like rescheduling would come with,

01:43:58.590 --> 01:44:12.640
Shane Pennington: you know, appropriations from Congress or something, so they, their budget would remain the same, and it would take a great outlay of resources in order for them to vigorously enforce the FDCA against cannabis. In general, I'm not that concerned about like, you know, an FDA
Shane Pennington: take over if we were to see rescheduling. There's a slight difference there with descheduling which again, I'm that's the position I think is best. I just want to clarify that once you remove DEA from the equation with descheduling that makes FDA the like the chief Federal agency with authority over the substance. Basically, I mean, others do to like the IRS and others, and whatever. But really

Shane Pennington: FDA would then, so if a Senator wants to drag somebody in front of them to answer questions about this cannabis industry that they don't like, you know, or whatever, they now they would go to DEA, because it's a controlled substance. But if DEA were out of the mix because it was descheduled,

Shane Pennington: that that Senator would be calling on you know someone from FDA to come, or HhHS to come talk to them about that, and I think that that is something that's probably maybe in the back of to the extent that FDA really considers, considering the scheduling, I think that might be in the back of their mind. Do they want to be

Shane Pennington: the in the spotlight like that on this substance that maybe they don't have the appetite or given no indication that they have the appetite to enforce against.

Cat Packer: Yeah, I think that that's helpful. It also kind of gets that this question that I think folks in like these criminal justice and social justice circles are talking about as we talk about marijuana reform. And it's like, are we going to treat this as a criminal justice issue or a public health issue. And I think you know,

Cat Packer: the the agency in charge is largely gonna dictate the approach that gets taken. But, as is you suggested, I think that there are different agencies that they could be ultimately tasked with that responsibility. Ultimately, I think that this may be an area that we need Congress to have some proactive legislation on.

John Hudak: Cat, could I just jump in quickly? You know one of the things I've I've beaten this horse a lot in my writing, and I know others on this panel have as well. One of the

John Hudak: things that worries me the most about legalization, and I'm someone who supports federal legalization, is the lack of preparedness that the Federal Government has for that day to come, and I think one of the things, one of the big takeaways for me from this panel is that we have parts of federal policy, I'll say policy, because there's law, and there's there's regulation, in which
John Hudak: the references to cannabis flow entirely through blanket statements about relationships to the Controlled Substances Act. There are other areas of policy in a variety of federal agencies that, as others have said on the call, have very specific cannabis related rules, and so simply legalizing cannabis doesn't undo all of the knots that exist in a lot of Federal agencies, and I think we often under appreciate how many different Federal agencies touch cannabis in certain ways. And so I'll give you very briefly an example of something that happened in Maine a few weeks ago.

So for those of you who are unaware, customs and border protection in the US does not just exist at the borders and in airports. They have jurisdiction within 75 miles of international borders and navigable waters. And so they set up interior enforcement checkpoints, and so a licensee in Maine was delivering cannabis from his cultivation facility to retail stores in the State, and his vehicle entered an interior immigration checkpoint, and all of his product and cash were seized, and his product was destroyed by customs and border protection. His cash is eventually supposedly going to be returned to him. But he was trafficking in a schedule one substance, and so Federal officials stepped in. Now my guess is, I don't know what the rules exist within customs and border protection, I would bet that it is attached specifically to a schedule one substance but I'm not sure of that. And I think there's a lot of things that individually, there are a lot of experts who are very sure about the narrow specifics that they they look at, but we really don't know what the implications or lack of implications are by federal legalization, whether it's through the administrative process or through a legislative process. And so I know a lot of people in the advocacy community sort of turn their noses up at the idea of a study committee of this. But a study committee is absolutely essential if we want any efficient, wide scale, broad-based Federal reform to happen. So we can look at all of these particulars because cannabis has been institutionalized into the Federal, into federal policy for decades in ways that we just don't even fully understand at this point. And I think this this panel, my colleagues on this panel have done a great job today of really highlighting just how intricate all of those things are in ways that we just don't fully understand.
Cat Packer: Thanks, John. I agree. I mean, I think, we do need to get better prepared for what's on the horizon, and there are all of these different implications.

Cat Packer: I don't disagree with this idea of a commission. My concern is that we talked about how the US had a commission before and how it disregarded the recommendation. If it had followed the recommendation of the original Commission, we may not be in this place in the first place, and unfortunately it seems as though our policies on cannabis in this country continue to be driven by politics.

Cat Packer: rather than rational science or or public policy priorities. That being said, I really appreciate folks time and walking through the different issues that I considered a priority. But I do want to ask two more questions of each of the panelists.

Cat Packer: First, we can see on the screen. This is a statement that President Biden had put out actually, before he took office, while he was running for President, articulating where he stood on marijuana laws. I'm curious, in your opinion panelists, would rescheduling or descheduling, or or what would be necessary for President Biden to keep his promises as he's made them today, or or here on cannabis. Is he able to keep his promises on marijuana reform if we move to schedule 3?

Cat Packer: And anyone.

Robert Mikos: I'll hazard, yeah, a solid no vote there.

Robert Mikos: I think, really, that the key point I want to get across is that Biden can't do this himself.
Robert Mikos: Most of these goals, if not all of them, would require Congressional legislation. So to the extent that President Biden can work with Congress, try to strike some deal, try to get the ball moving there,

01:51:47.360 --> 01:52:03.949
Robert Mikos: he could fulfill these promises, but he can't do this unilaterally. I know that that was certainly true, there, there were other Presidential aspirants who over promised to an even greater extent on the campaign trail. Bernie Sanders, Elizabeth Warren, for example said

01:52:03.950 --> 01:52:31.519
Robert Mikos: first day in office, first thing I'm gonna do is totally legalize marijuana and you just can't do that. We've talked about the constraints on the executives authority, and those constraints are are pretty potent. There's there's no unilateral way around them. So you gotta work with Congress. That's the only way to get it done, and it's probably going to take something more than Congressional legislation that says, move marijuana to to schedule 3. But any way you accomplish that is, is going to require some Congressional input.

01:52:32.020 --> 01:52:45.749
Cat Packer: Thanks, Rob, I think, for the purpose of time, if folks could answer the question and then also respond with their their one piece of advice for the Biden Administration or Congress on Federal marijuana reform. So

01:52:47.030 --> 01:52:50.139
Cat Packer: Shane? You're you're in the hot seat.

01:52:51.170 --> 01:52:58.500
Shane Pennington: Yeah, no problem.

01:52:58.580 --> 01:53:03.249
Shane Pennington: Legalize it. I mean, that's that's my advice. And that means working with the States,

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Shane Pennington: push to get the information they need to regulate responsibly which they do not have now. They should be talking to people like John Hudak and Robert Mikos about, you know, and to all State regulators, and to to other stakeholders, people on the ground who know what's going on with this and getting the information.

Shane Pennington: And they they should be doing it post haste and Congress should prioritize it. Because this is a is a mess that's not going to, we're not going to get out of
Shane Pennington: simply or easily. It's going to take a lot of effort. And there's kind of a breakdown in how the information normally flows. Normally, you know the States are the laboratories of democracy, and we all benefit from seeing how those experiments play out and the Federal Government gets the information from the States, and we go and we improve over time. But with cannabis it's not like that, because the States are not, you know, incentivized to communicate. And the Federal Government isn't listening. And we just continue to have this huge gap in state and Federal policy which undermines the rule of law. And it's basically, you know, unamerican.

Shane Pennington: And so yeah, I mean, I hope that they do that. I hope they do it soon. It's important to understand that as historic as this process is, and as grateful as we should be for the incremental victories that we get like like everyone's been saying. I mean, it will not accomplish the

Fatima Afia: Yeah. So unfortunately, much like Shane and Rob, my answer is that no rescheduling does not get us to where Biden has promised he would get us. I agree that we definitely need comprehensive legislation, and the Biden Administration should really work with Congress, work with States, work with state regulators in particular. You know CANORA, they already, all the Cannabis Regulators of America, they're already working with each other

Fatima Afia: because they are anticipating federal legalization right? And so there are State regulators that already have these sorts of plans in mind, but they need the Federal Government to step in and guide them as to what it is of the Federal Government is actually anticipating on doing, because if they are just talking to themselves, but they're not talking to the Federal Government, there's a really big disconnect there.

Fatima Afia: And so, you know, and we're going to start seeing by the way, you know, in anticipation of eventual legalization, we're going to start seeing States
Fatima Afia: enter into semi, not formal but semi interstate compacts where they're going to start engaging in intercommerce with each other on small levels, to sort of test the waters, and maybe even push the Federal Government to do something.

01:55:42.190 --> 01:56:07.189
Fatima Afia: And so it's really incumbent on the Biden Administration and Congress to anticipate these situations happening and working with the States and working with stakeholders, small businesses, big businesses, you know we already are seeing lobbying efforts by the tobacco and alcohol industries who know that this is coming, and they want to be first in line, and so small businesses also need to be front and center in these conversations to make sure that all the businesses

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Fatima Afia: that are currently operating in state, legal jurisdictions don't get completely decimated once federal legalization is here. So that would be my advice.

01:56:17.370 --> 01:56:18.640
Cat Packer: John?

01:56:20.060 --> 01:56:24.270
John Hudak: Yeah, I agree with what everyone has said so far. What what I'll add is that

01:56:24.280 --> 01:56:43.679
John Hudak: my advice for the for the Biden Administration, and frankly, anyone who's interested in in taking this issue on, is to just get better informed about it. One of the things that has shock to me is that Presidential candidates, gubernatorial candidates, candidates for Congress,

01:56:43.690 --> 01:56:50.759
John Hudak: are just so staggeringly ignorant about the realities of cannabis policy, and

01:56:50.780 --> 01:57:05.130
John Hudak: how their ideas might actually get transformed into reforms. And it it's true of the President, it was true of the previous President, it was true of the President before him, and all the rest before them. And so one of the

01:57:05.500 --> 01:57:11.789
John Hudak: one of my worries when it comes to cannabis policy, and I touched, cannabis reform rather, and I touched on this earlier is

01:57:11.910 --> 01:57:15.930
John Hudak: a lot of it's bumper sticker politics and policy.
John Hudak: The reason we're in this mess is because cannabis was initially bumper sticker politics and policy. It's bad. It'll turn into a murderer. It's it's kill, it's corrupting our youth. Those are all really quaint bumper stickers. The solution to that is not more bumper stickers in the other direction. It's actually putting in the hard work of crafting policy, understanding how that policy gets executed.

John Hudak: understanding the role of Federalism in this process and putting all of those ideas together into realistic legislation and realistic reform. The President's not going to be able to do all of the things that are on this list. A President's not going to be able to do the things, as as Rob mentioned earlier, that Senator Sanders and others have said that they would do. It's a matter of just really understanding what cannabis policy is and how it needs to be changed.

Cat Packer: Thanks, John. Patti?

Patti Zettler (she/her): Well, I know we only have 2 min left, so I'll just say I echo what everyone said, and particularly John's comments about how complicated everything is, and and how things are so inner related, so I hope to see a more comprehensive approach than, than, even if descheduling or rescheduling is a necessary part of that comprehensive approach, to see a comprehensive approach.

Cat Packer: Thank you. For me, personally, I think, for the Drug Policy Alliance, the Cannabis Regulators of Color Coalition that I represent, we want to see full descheduling. We want to see that coupled with comprehensive legislation. For us, we we think that both the President and Congress have both an opportunity and responsibility to push reform. I think that even if we land on a rescheduling decision, there's more that the President can do. I mentioned in in part the publication, Equity Action Plan for Marijuana Reform, and I think this gets at part of what everyone has mentioned here today, which is that there are many more steps. The Biden Administration announced 3 steps, but we need a thousand steps. And part of my priority, as an advocate and reformer in this space is to
Cat Packer: ensure that the steps that we take are equity centered. And in order for us to do that, we have to have data, we have to be able to understand how cannabis policy is impacting stakeholders, how it's impacting issues. We know that those impacts today immense. I really appreciate everyone's time, the panelists for volunteering their time and expertise. I know that we didn't get to many of the questions, but I will be working

01:59:53.570 --> 02:00:03.169
Cat Packer: with the university to collect those questions to put out responses. So thank you so much for your time. And I'll pass things back over to Holly.

02:00:06.940 --> 02:00:16.679
Holly Griffin: Thank you, Cat. I think we're all set for today. Everyone registered for this event will receive a link to the recording when it is available, hopefully early next week. And thank you again for joining us.