



Commercializing Cannabis in the Face of Regulatory Uncertainty

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Cannabis—State Regulation and Licensing



Sativa Rasmussen



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Helpful Terminology

1. What is cannabis?

- A plant genus within the Cannabaceae family that includes multiple species, including *Cannabis sativa L.*, *Cannabis indica*, and *Cannabis ruderalis*.
- Think of “Cannabis” as an umbrella term encompassing both “marijuana” and “hemp.”

2. What is marijuana?

- Schedule I narcotic under the Controlled Substances Act (“CSA”), meaning there is no currently accepted medical use and high potential for abuse.
- Under the CSA, *Cannabis sativa L.* and any compounds.
 - Does NOT include “hemp” after passage of the 2018 Farm Bill.

3. What is “hemp”?

- “*Cannabis sativa L.* and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.”



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Helpful Terminology

4. What are cannabinoids?

- Naturally occurring compounds found in the cannabis plant.
- Interact with receptors in our body's endocannabinoid system.
- Over 60 known cannabinoids.

5. What is CBD?

- One of the most well known cannabinoids found in the cannabis plant.
 - Occurs in both marijuana and hemp.
- No psychoactive effect.



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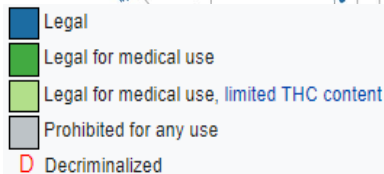
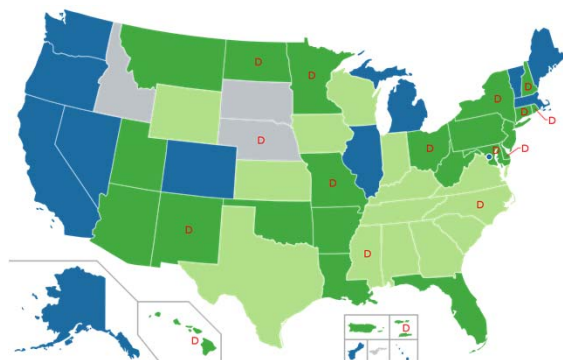
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Current Status of Marijuana

State Laws

- Recreational: 11 states + D.C.
- Medicinal: 33 states
 - Including recreational states



Map from Wikipedia



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COVID-19 Impacts on Marijuana

- **Recreational Marijuana Businesses**
 - **States with “Essential” Designation**
 - A total of 9 states have made this determination
 - WA, OR, CO, IL, CA, AK, MI
 - NV only permits delivery
 - **“Non-Essential” Classification**
 - To date, Massachusetts and Vermont are the only adult-use states that have deemed marijuana retailers as “non-essential.”
 - Both continue to allow medical marijuana
- **Medical Marijuana Businesses**
 - No states (with a medical marijuana program) that have issued stay-at-home orders have prohibited medical marijuana businesses from serving patients.



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Current Status of Hemp

2014 Farm Bill

- Authorized institutions of higher education and states departments of agriculture to implement pilot programs to research industrial hemp.
- Many states interpreted research to encompass research related to commercial activities.
- Did NOT remove hemp from the CSA and did not give any federal agency regulatory authority over hemp.

2018 Farm Bill

- Explicitly removed hemp and its byproducts from the definition of “Marijuana” in the CSA and broadened the pilot programs to allow for more widespread non-academic cultivation of hemp.
- Directs the U.S. Department of Agriculture (USDA) to issue regulations and guidance to implement a program for the commercial production of industrial hemp in the United States.
- All State and Tribal plans are to be submitted to the USDA for review and approval.
- Offers protections for interstate transportation of hemp or hemp products
- Required the USDA to establish a plan to monitor and regulate the production of hemp in those States or Indian tribes that do not have an approved State or Tribal plan.



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USDA Interim Final Rule

- **Interim Final Rule (“IFR”)**
 - Outlines provisions for USDA to approve plans submitted by states and Indian tribes for the domestic production of hemp
 - It also establishes a federal plan for producers in states or territories of Indian tribes that do not have their own USDA-approved plan
 - Requirements for testing, destruction of products, sourcing hemp seeds, etc.
- **Enforcement Discretion Update**
 - Announces delayed enforcement of certain requirements in the IFR
 - DEA registered testing labs
 - Less than 50 in the US
 - Disposal of non-compliant hemp
 - In place until the final rule is published, or Oct. 31, 2021, whichever comes first



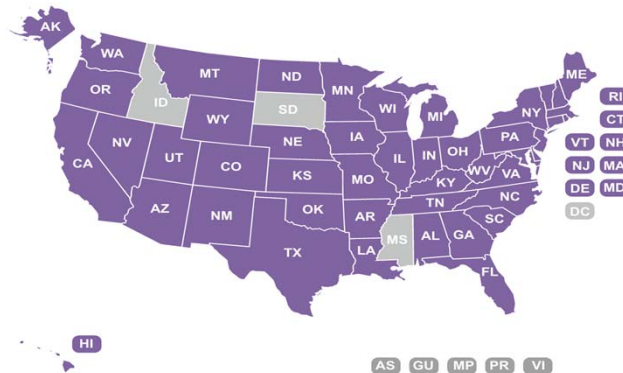
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State Industrial Hemp Programs

Allows cultivation of hemp for commercial, research or pilot programs Does not allow cultivation of hemp.



Source: National Conference of State Legislatures. State Industrial Hemp Statutes – February 25, 2020



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Current Status of Hemp

- **USDA approved hemp production plans under the IFR**
 - 16 states have received approval
 - 4 state plans currently under review
 - 20 Tribal plans have been approved
 - 13 Tribal plans currently under review
- **18 states have elected to continue to operate under existing 2014 pilot programs for the 2020 harvest season**

Food, Drug, and Cosmetic Act

- **The 2018 Farm Bill and the Interim Final Rule have no bearing on the Federal Food, Drug, and Cosmetic Act (“FD&CA”)**
- **The 2018 Farm Bill explicitly preserved the Food & Drug Administration’s (“FDA”) authority to regulate products containing cannabis or cannabis-derived compounds under the FD&CA**
 - Those marketed as food, dietary supplements, drugs, and cosmetics
- **Generally Recognized As Safe (“GRAS”) Hemp Products**
 - Hulled hemp seed
 - Hemp seed protein powder
 - Hemp seed oil

Food & Drug Administration's Policy on CBD

“It is currently illegal to market CBD by adding it to a food or labeling it as a dietary supplement.”

- **Food and Dietary Supplement Concerns**
 - Safety and efficacy
 - Interactions with prescription medications
 - Dosage considerations
 - Methods of consumption
 - Effect of CBD on different populations (children, pregnant women, etc.)
- **What about cosmetics?**
 - Not subject to premarket approval by the FDA (except most color additives)
 - Certain cosmetic ingredients are prohibited or restricted by regulation, but currently that is not the case for any cannabis or cannabis-derived ingredients.



Source: *What You Need to Know (And What We're Working to Find out) About Products Containing Cannabis or Cannabis-derived Compounds, Including CBD*, Food & Drug Administration

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States Allowing CBD in Food

- **Despite the FDA's position on the use of CBD in food products, several states have passed legislation to allow sales of such products**
 - Colorado
 - Florida
 - Oregon
 - Texas
- **Some states have also passed laws to allow for hemp and hemp-derived CBD to be sold into the recreational marijuana market**
 - Oregon
 - Washington



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Litigation and Enforcement



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FDA Regulation of CBD

- A “drug” is an article “intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals” or “intended to affect the structure or any function of the body of man or other animals” or intended for use as a component of such article. 21 U.S.C. § 321(g)(1)
- A “new drug,” with a few exceptions, is a drug that is “not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof.” 21 U.S.C. § 321(p)(1)



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FDA Regulation of CBD

- **“No person shall introduce or deliver for introduction into interstate commerce any new drug,” absent an effective filing of a new drug application.** 21 U.S.C. § 355; *see also* 21 U.S.C. § 331(d)
- **A drug is “misbranded” unless its labeling “bears adequate directions for use.”** 21 U.S.C. § 352(f)(1)
- **“Adequate directions for use means directions under which the layman can use a drug safely and for the purposes for which it is intended.”** 21 C.F.R. § 201.5
- **Directions are *per se* inadequate if the condition a drug is intended to address is not amenable to self-diagnosis and treatment by a layperson.**



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FDA Regulation of CBD

- **It is a “prohibited act” to introduce into interstate commerce “any food to which has been added a drug approved under [21 U.S.C. § 355]” or “for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public.”**
21 U.S.C. § 331(II)
- **CBD is the active ingredient in the approved drug Epidiolex.**
- **Several clinical investigations of CBD have been made public.**
- **FDA therefore considers foods containing CBD to be “adulterated.”**



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FDA Regulation of CBD

- A “food additive” is a substance that, in its intended use, becomes a component of any food, if it “is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures . . . to be safe under the conditions of its intended use.” 21 U.S.C. § 321(s)
- Absent premarket approval or an exemption, food additives used in food are deemed to be unsafe. 21 U.S.C. § 348(a)
- An unsafe food additive “shall be deemed to be adulterated.” 21 U.S.C. § 342(a)(2)(C)(i)
- It is prohibited to introduce an adulterated food product into interstate commerce. 21 U.S.C. § 331(a)



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FDA Regulation of CBD

- A “dietary supplement” does not include “an article that is approved as a new drug under section 355 of this title” or “an article authorized for investigation as a new drug, antibiotic, or biological for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public.” 21 U.S.C. § 321(ff)(3)(B)



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FDA Enforcement

- **Warning Letters**
 - “informal and advisory”
 - not final FDA action
- **Enforcement Actions**
 - **Seizures**
 - **Injunctions**
 - **Criminal fines and imprisonment**
 - **Misdemeanors do not require proof of intent. Fines up to \$100,000 for individuals and \$200,000 for corporations in the absence of a death and/or up to a year in the clink.**
 - **Felonies can lead to fines up to \$500,000 and/or incarceration of up to 3 years.**



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FDA Enforcement

- **FDA Can't Do It All:**

“People are using these products. . . . We're not going to be able to say you can't use these products. It's a fool's game to try to even approach that.” -FDA Commissioner Dr. Stephen Hahn
- **Enforcement to date:**
 - **CBD touted on labels/advertising/social media as treatment for cancer, hepatitis, Tourette Syndrome, mad cow disease, multiple sclerosis, arthritis, heart disease, Alzheimer's, Lyme disease.**
 - **CBD touted as a “cure” for Covid-19: “CBD CAN PREVENT AND CURE THE CORONAVIRUS!”**



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CBD Lawsuits

- Lawsuits claiming products contain less CBD than labeled or advertised.
- Lawsuits claiming CBD products are ineffective or unsafe.
- Lawsuits claiming products are deceptively labeled or advertised.
- Lawsuits claiming products are unlawful and therefore worthless.



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Defenses and Problems of Proof

- Problems proving ineffectiveness or injury.
- Problems showing deception/reliance.
- Problems showing a price premium.
 - *But see Debernardis v. IQ Formulations, LLC*, 942 F.3d 1076 (11th Cir. 2019)
- Preemption/no private right of action.
 - *See, e.g., PDK Labs, Inc. v. Friedlander*, 103 F.3d 1105 (2d Cir. 1997)
- Primary Jurisdiction Doctrine
 - *See, e.g., Snyder v. Green Roads of Florida, LLC*, 2020 U.S. Dist. LEXIS 1145, 2020 WL 42239 (S.D. Fla. Jan. 3, 2020)



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The Continuing Federal Criminal Law Quandary



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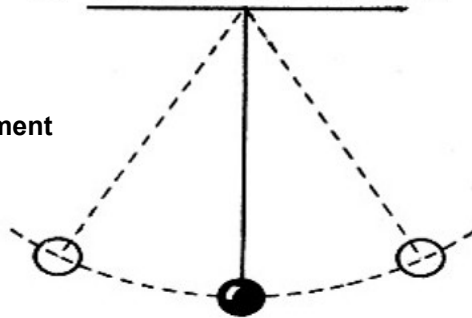
The Banking Quandary

There continue to exist federal roadblocks to state-licensed cannabis businesses—both medical and recreational

Pendulum

Risk Management

Jail Time



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Cannabis Legal Background

- Legal or not under state law—the cultivation, distribution and sale of cannabis remains illegal under federal law
- Federal anti-money laundering laws apply to violations of federal drug laws
- Potential asset forfeiture and aiding and abetting liability for federal drug violations
 - Criminal penalties and fines
 - Conspiracy liability
 - Accessory after the fact liability
- Supremacy Clause of U.S. Constitution
 - Federal criminal law applies regardless whether state law is silent or specifically permits activity
 - *Intrastate* activity an irrelevancy
 - But may diminish intent to violate the law....



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The Cole Memorandum—RIP—Maybe...

- The Cole Memorandum—August 29, 2013
 - Provided list of CSA of cannabis enforcement priorities for Department of Justice attorneys and law enforcement
 - Bad v. really, really bad activity dichotomy
 - Rescinded by the former Attorney General on January 4, 2018
 - Current status is that traditional DOJ prosecutorial guidelines apply



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The Cole Memo Priorities

- **Preventing—**
 - The distribution of cannabis to minors
 - Cannabis revenue from going to criminal enterprises and cartels
 - The diversion of cannabis from states where it is legal under state law in some form to other states
 - State-authorized marijuana activity from being used as a cover for the trafficking of other illegal drugs or other illegal activity
 - Violence in the cultivation and distribution of marijuana
 - Drugged driving and the exacerbation of other adverse public health consequences associated with marijuana use
 - The growing of marijuana on public lands and the attendant public safety and environmental dangers
 - Cannabis possession or use on federal property

The Cole Memo Priorities



**Anything Tony Would
Approve of—
Probably Violates the
Cole Memo...**

FinCEN-2014-G001

BSA Expectations Regarding Cannabis-Related Businesses

- Clarifies how financial institutions can provide services to cannabis-related businesses consistent with their BSA obligations
- Reiterates Cole Memo priorities (which has been rescinded)
 - Imposes on-going due diligence on banks electing to bank cannabis businesses
 - Expands the Cole Memo list of **red-flags** to 22
- Creates three new types of SARs



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FinCEN-2014-G001

Types of Marijuana SARs



- **Marijuana Limited** – no Cole memo implications, no state law violations
 - Identify subject and related parties
 - Provide addresses
 - The filing is derived solely from marijuana-related business activities
 - No additional suspicious activity has been identified
 - Narrative section – “MARIJUANA LIMITED”



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FinCEN-2014-G001 Types of Marijuana SARS

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- **Marijuana Priority – implicates Cole Memo or violates Utah law**
 - Needs all information required in limited filing
 - Details on the enforcement priority implicated
 - Dates, amounts, and other relevant details of financial transaction
 - Narrative section – “MARIJUANA PRIORITY”

FinCEN-2014-G001 Types of SARS Marijuana SARs

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- **Marijuana Termination – If a bank deems it necessary to close an account of a marijuana-related business for compliance purposes**
 - Include the basis for termination
 - Narrative section – “MARIJUANA TERMINATION”
 - If a bank is aware that a cannabis business is moving accounts to a specific alternative institution then the bank is “urged” to alert the other institution
- **Section 314(b) authority to voluntarily disclose**

FinCEN Due Diligence Requirements

- **Verify whether the business is duly licensed and registered**
- **Review the license application (and related documentation) submitted by the business for obtaining a state license to operate its cannabis-related business**
- **Request from state licensing and enforcement authorities information about the business and related parties**
- **Assess the normal and expected activity for the business, including the types of products to be sold and the customers to be served (e.g., dispensing medical or recreational cannabis)**
- **Monitor publicly available sources for adverse information about the business and related parties**
- **Monitor for red flags, including red flags identified by FinCEN**
- **Refresh information obtained as part of customer due diligence on a periodic basis and commensurate with the risk**
 - At least every 90 days

On-Going Due Diligence

- **The FinCEN Guidance requires that a Limited Marijuana SARs must be updated every 90 days**
- **FinCEN has clarified this guidance by indicating that banks with on-going SAR requirements must file an updated SAR for continuing activity after a 90-day review—with the filing deadline being 120 days after the date of the previously related Limited Marijuana SAR**
- **This means that a minimum of 4 SAR updates are required in a calendar year**
- **The complicated nature of many state laws present significant compliance challenges—**
 - Which explains why many banks avoid companies that “touch the plant”

FinCEN's Policy Position

- FinCEN has consistently indicated that FinCEN-2014-G001 was intended to authorize and encourage banks to open accounts for “lawful” cannabis entities
 - FinCEN has announced that its guidance *continues* to apply
 - No DOJ enforcement action to date except for traditional cannabis criminal activity



But FinCEN's Guidance Goes So Far...

“The SAR reporting structure laid out in FinCEN’s February 14, 2014 Guidance “BSA Expectations Regarding Marijuana-Related Business” remains in place, and that SAR reporting guidance with regard to financial institutions seeking to provide services to marijuana-related businesses applies to the specific facts and circumstance set forth in that document. Situations not specifically addressed in that guidance should be treated under standard SAR reporting rules and related guidance. The manufacture, distribution, and dispensing of marijuana is an illegal act in violation of federal law. FinCEN will continue to work closely with law enforcement and the financial sector to combat illicit finance. We will notify the financial sector of any changes to FinCEN’s SAR reporting expectations.”

Deposit and Lending Issues

- Credit underwriting
 - Cannabis revenue analysis
 - Tax considerations
 - IRS Section 503E
- Deposit
 - Concentration
 - Sticky deposit analysis
- Loan documentation
 - Reps and warranties
 - Agreement to provide access and cooperation
- Secured financing
 - Personal property
 - Real property
- Foreclosure, insolvency and litigation
 - [*In re Rent-Rite Super Kegs W. Ltd.*, 484 B.R. 799, 809 \(Bankr. D. Colo. 2012\)](#)
 - *Garvin v. Cool Investments NW*, No.18-352119 (May, 2019, 9th Cir.)
- Bank regulatory agency examinations
- Interstate and cross-border movement of cannabis-related products and revenues



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Deposit and Lending Issues

- Hemp products
- Investment and securities law considerations
 - SEC disclosures
 - Broker-dealer obligations
- Insurance
 - D&O coverage
 - Fidelity bonds
 - Defense costs
- Profitability
 - Fees and charges
- Employment issues
 - Corporate policy guidance
- Legal Opinions



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The Best Practices Goal—The Gold Standard

- The U.S. Sentencing Commission (an independent agency in the judicial branch) has promulgated a series of guidelines to determine whether an effective compliance and ethics program is operating for potential corporate offenders
 - <https://www.ussc.gov/guidelines/2015-guidelines-manual/2015-chapter-8>
 - The Commission Guidelines have become the “gold standard” for evaluating the effectiveness of a corporate compliance and ethics program—compliance with which evidence an intent not to violate the law
 - We suggest that the Bank should regularly evaluate its cannabis policies and procedures to determine whether its compliance program meets the Commission Guidelines
- To meet the Commission Guidelines for an effective compliance and ethics program, the Bank must:
 - Exercise due diligence to prevent and detect criminal conduct, and
 - Otherwise promote an organizational culture that encourages ethical conduct and a commitment to compliance with the law

The Best Practices Goal—The Gold Standard

- The Commission Guidelines identify seven factors to be considered:
 - (1) The Bank must establish standards and procedures to prevent and detect criminal conduct
 - (2) The Bank’s senior management and Board of Directors must be knowledgeable about the content and operation of the compliance and ethics program and must exercise reasonable oversight with respect to the implementation and effectiveness of the compliance and ethics program
 - Specific high-level personnel within the Bank should be assigned overall responsibility for the compliance and ethics program
 - (3) Employees known to have engaged in illegal conduct cannot participate in the compliance program

The Best Practices Goal—The Gold Standard

- (4) The Bank must conduct training for all levels of its personnel regarding the components of the compliance and ethics program
- (5) The Bank must take reasonable steps—
- To ensure that the Bank’s compliance and ethics is followed, including monitoring and auditing to detect criminal conduct
 - To periodically evaluate the effectiveness of the Bank’s compliance program organization’s compliance and ethics program, and
 - To create and to publicize a system whereby the Bank’s employees and agents may report or seek guidance regarding potential or actual criminal conduct without fear of retaliation
- (6) The Bank’s compliance and ethics program should be promoted and enforced consistently throughout the organization through both appropriate incentives and appropriate disciplinary measures to ensure compliance
- (7) After criminal conduct has been detected, the Bank must take reasonable steps to respond appropriately to the criminal conduct and to prevent further similar criminal conduct, including making any necessary modifications to correct any identified deficiencies

Recent Federal Developments

- **The SAFE Banking Act**
 - H.R. 1595
 - <https://www.congress.gov/116/crpt/hrpt104/CRPT-116hrpt104.pdf>
 - Passed the House Financial Services Committee
- **Strengthening the Tenth Amendment Through Entrusting States Act of 2018**
 - S. 1028
 - Sponsored by Senators Warren and Booker

Recent Federal Developments

- **Senate Banking Committee Hearing on July 22nd**
 - No specific legislation addressed
 - No Republicans attended except Senator Crapo
 - <https://www.banking.senate.gov/hearings/challenges-for-cannabis-and-banking-outside-perspectives>
- **Joint Statement on Risk-Focused Bank Secrecy Act/Anti-Money Laundering Supervision**
 - July 22, 2019
 - <https://www.federalreserve.gov/newsevents/pressreleases/files/bcreg20190722a1.pdf>

Questions?

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We will send CLE Certificates to those who return the form.



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Questions



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