FDA Public Hearing
Scientific Data and Information about Products Containing Cannabis or Cannabis-Derived Compounds

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Speaking on My Own Behalf

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Background and Disclaimer

- Speaking on my own behalf – not my firm / client / association
- FDA and IP Attorney (biochemistry)
- Worked at FDA 1991-2000 – Office of the Commissioner & CDER
- Worked at FDA/IP Boutique and large law firms – currently Arent Fox LLP
- Active in bar associations, particularly NYSBA and FDLI
  - NYSBA / Co-Chair Committee on Cannabis Law; Chair, Food, Drug and Cosmetic Law Section and Member of NYSBA's legislative committees
  - FDLI / Cannabis-Derived Products Committee (new)
- Law firm: Arent Fox LLP / Cannabis industry group & range of cannabis or cannabis-derived product clients in FDA- or State-regulated space

Overview

- How I Got Involved in Cannabis and FDA
- Cannabis Clients and Overlay with FDA
- Law Firms with Cannabis Industry Groups
- Need for FDA Client Guidance Increasing
- Questions

How I Got Involved in Cannabis and FDA

- NYSBA Annual Meeting (January 29, 2015) - Food, Drug and Cosmetic Law Section "Through the Smoke: Attorney Ethics in Representing Clients in the Medical Marijuana Industry" – focus on NYSBA Ethics Opinion, Cole Memo, fed/state issues
- Various NYSBA Cannabis-Related CLE Programs: Various sections had their own CLE programs but movement to coordinate in a committee prior to a new section to engage all related legal disciplines and create thought leadership for developing legal field as well as develop training materials and maintain attorney ethics given federal/state issues
- June 2017 Pitched to NYSBA Executive Committee Concept of New Committee on Cannabis Law – Approved!!! New members appointed late 2017 – Co-Chair and added an academic advisor.

How I Got Involved in Cannabis and FDA (cont'd)

- Mission
  - The **Committee on Cannabis Law** is charged with serving as the New York State Bar Association's focal point for the evolving legal status of Cannabis at both the state and federal level. Cannabis law is perhaps one of the fastest growing yet complex areas of the law that poses a broad spectrum of challenges. This Committee seeks to help NYSBA lawyers give their clients better advice through sharing educational resources, and otherwise helping New York set the highest possible legal and business (including advice to medical professionals) standards for legalized Cannabis products.

How I Got Involved in Cannabis and FDA (cont'd)

- Committee on Cannabis Law Activity Summary
  - 2018
    - January 2018 NYC Annual Meeting – Cannabis Law in US and NY Overview
    - May 2018 Albany - Legislative Developments Medical Marijuana and Hemp
    - August 2018 - Medical Marijuana Perspectives (medical and growers) and Adult Use
    - October 2018 – Implications of Decriminalized Marijuana (FDA and clinical research)
  - 2019
    - January 2019 Annual Meeting – Hot Topics including CBD/Cannabis Packaging/labeling
    - Legislative Comments on CRTA / FDA written / Committee Report in development
    - May 2019 Hot Topics - New York's CRTA/MRTA, Diversity, Ethics, Advertising, & M&A
    - Upcoming September 2019 Buffalo – Hemp Focus

Cannabis Clients and Overlay with FDA

- Since 2015 NYSBA Program – increasing client base both on international and state-medical marijuana growing and dispensary programs – others desired but frustrated with limited research and many federal v. state issues including banking and marketing
- Since 2018 Farm Bill increasing companies seeking to enter cannabis product market, primarily hemp-derived (foreign and domestic) often with first goal to enter state-friendly markets and then interstate commerce following FDA review and development of guidance
- State programs a patch work – some defer to FDA or identify certain products that may not contain cannabis-derived products (e.g., food) whereas others silent, some with seeming overlapping product authority

Law Firms with Cannabis Industry Groups

- Initially many smaller firms added cannabis practice, some cannabis law boutiques in states with more developed programs with focus on state program entry and compliance
- Larger law firms adding cannabis groups – multidisciplinary approach, some building on tobacco or alcohol practice groups or core strengths
- Initial issues with company diligence / banking – larger players finding banks willing to work with them and other banking options such as M&A, including newer cyber currencies and investment options
- Potential ethics issues continue post Cole Memorandum rescission with limited engagement options

Need for FDA Client Guidance Increasing

- December 2019 Farm Bill created more confusion – what is now “legal” ?
- FDA can help cannabis-derived companies (and states) struggling with:
  - Cannabis ingredient terminology such as:
    - Cannabidiol (CBD) – “CBD extract”, “CBD oil”; “broad/full spectrum” CBD (means?)
    - “Hemp extract”, “hemp oil” (e.g., hemp seed or plant?)
    - “THC free” (e.g., less than 0.3% or lower?)
  - Laboratory testing accreditation for cannabinoids (CBD/THC) and thresholds
  - Intermediary processing and THC testing, e.g., cannabis/hemp biomass and the potential shipment of it in interstate commerce for further processing
  - What cannabis- or hemp-derived products may be used in all FDA-regulated products including over-the-counter products such as cosmetics, drugs, and medical devices and whether cannabis ingredient terminology or CBD/THC threshold amount matters

Need for FDA Client Guidance Increasing (cont'd)

- FDA can help cannabis-derived companies (and states) struggling with (cont'd):
  - Discuss whether dosage forms change the product category e.g., vitamins may be gummies or inhaled (B-12) or oils (vitamin E) - does a particular dosage form, e.g., vaped CBD, automatically make "hemp extract" or CBD a "drug" or "dietary supplement"?
  - Discuss whether there is a need for allergen testing for CBD (either for internal or external use) to determine safe levels or levels where adverse events may be observed - and does purity or "broad/full spectrum" matter, and should such testing requirement be triggered at a certain threshold amount of CBD?
  - Develop guidelines for cGMPs for cannabis-derived products and CBD in particular
  - Import/export implications for hemp and CBD used in FDA-regulated products, especially regarding documentation and labeling for US Customs and Border Patrol
  - Work with FTC to develop advertising guidelines for cannabis-containing/derived products and help states with their own programs
  - Work with states to develop more uniform labeling and packaging and guidelines for what is a state-only versus interstate commerce cannabis-containing/derived product

Questions

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