

FLAVOR WARS

Potential Anticipated and Unanticipated Impacts of FDA Bans on Characterizing Flavors in Cigarettes and Cigars

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*VCBH's 9th Annual Conference
Innovations in Tobacco Control
October 2021*



*Not long ago, not far away...
Tobacco products were
completely unregulated. After the
Master Settlement Agreement,
the tobacco industry expanded
its influence at the point of sale,
selling menthol cigarettes and
flavored cigars.*

*A rag tag groups of advocates
and localities fought to ban
flavored tobacco products.*

Meanwhile federal authorities

A New Hope

- 2009—FSPTCA calls for TPSAC report on menthol
- 2011—TPSAC Report
- 2013—FDA Report on menthol
- 2013—FDA ANPRM on menthol
- 2013—Citizen Petition to FDA on menthol
- 2015—~~Menthol~~ deleted from deeming rule
- 2018—FDA ANPRM on flavors
- 2018, Oct—Gottlieb said it was “a *mistake... to back away on menthol*”
- 2018, Nov—FDA announced plans to ban:
 - Menthol cigarettes
 - Flavored cigars
 - ECIG flavors

FDA STATEMENT

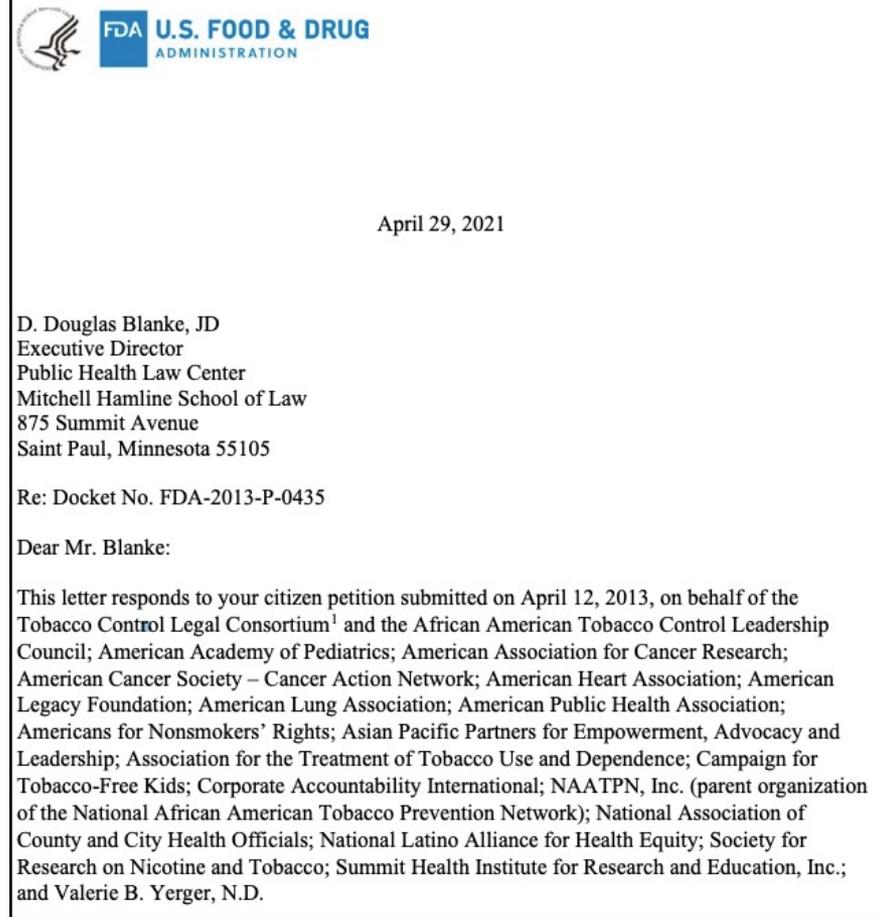
Statement from FDA Commissioner Scott Gottlieb, M.D., on proposed new steps to protect youth by preventing access to flavored tobacco products and banning menthol in cigarettes

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For Immediate Release: November 15, 2018
Statement From: Commissioner of Food and Drugs - Food and Drug Administration
Scott Gottlieb M.D.

Years Pass...

- 2020, June—Lawsuit asks FDA to respond to Citizen's Petition
- 2021, Jan—FDA responded that it would answer Citizen's Petition
- 2021, Jan—FDA requested 90 days to review additional evidence
- ***2021, April 29—FDA granted petition; stated it would begin rulemaking within 1 year***



Issuing a Product Standard (Or Two)

- FSPTCA Section 907
 - Authorizes FDA to issue a **product standard**
- FDA must consider:
 - **Risks** and **benefits** to population
 - Likelihood that (menthol) users will **stop** using them
 - Likelihood non-users will **start**
 - Technical achievability of standard
 - Any **countervailing effects**—e.g., creating a significant demand for contraband

Family Smoking Prevention and Tobacco Control Act

Section 907:

1) SPECIAL RULES.—

“(A) SPECIAL RULE FOR MENTHOL TOBACCO.—
 After the date of enactment of the Family Smoking Prevention and Tobacco Control Act, a cigarette or any of its component parts (including the tobacco, filter, or paper) shall not contain, as a constituent (including a smoke constituent) or additive, an artificial or natural flavor (other than tobacco or menthol) or an herb or spice, including, strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice chocolate, cherry, or coffee, that is a characterizing flavor of the tobacco product or tobacco smoke. Nothing in this subparagraph shall be construed to limit the Secretary's authority under this section or other sections of this Act applicable to menthol or any artificial or natural flavor, herb, or spice not specified in this subparagraph.”

“...a cigarette or any of its component parts (including the tobacco, filter, or paper) shall not contain, as a constituent (including a smoke constituent) or additive, an artificial or natural flavor (other than tobacco or menthol)...”

“Nothing in this subparagraph shall be construed to limit the Secretary's authority to take action under this section or other sections of this Act applicable to menthol or any artificial or natural flavor, herb, or spice not specified in this subparagraph.”

Potential Countervailing Effects

1. Flood of unregulated cigarettes
2. Increased sales to underage buyers
3. Make-your-own menthols
4. Criminalizing menthol cigarettes
5. Loss of tax revenue



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July 18, 2018

VIA ELECTRONIC SUBMISSION
AND HAND DELIVERY

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2017-N-6565 ("Regulations of Flavors in Tobacco Products")

Dear Sir or Madam,

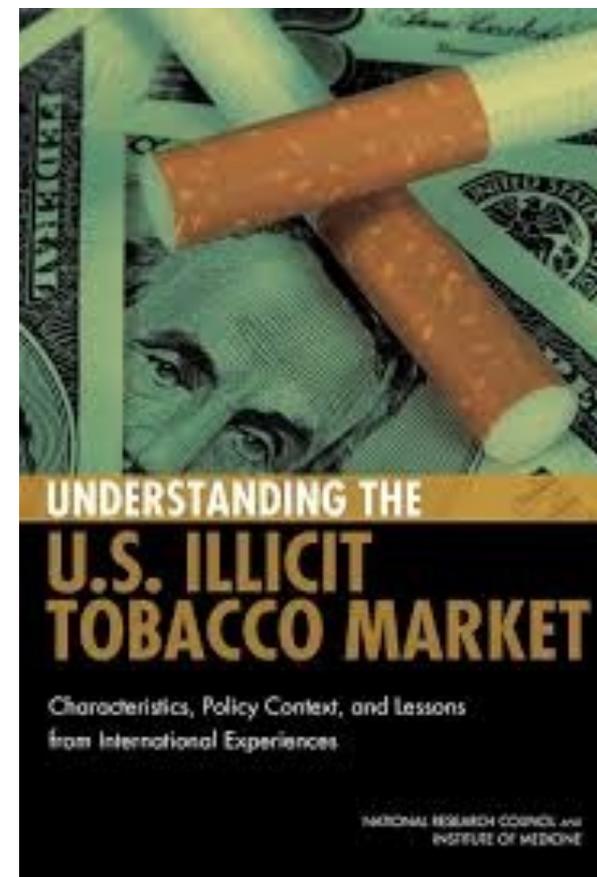
On March 21, 2018, the United States Food and Drug Administration ("FDA" or "the Agency") published an advance notice of proposed rulemaking ("ANPRM") seeking information related to characterizing flavors in tobacco products, entitled *Regulation of Flavors in Tobacco Products*, 83 Fed. Reg. 12294.¹ While the Agency requests information relating to menthol in cigarettes (albeit in one question), the majority of the ANPRM seeks information and comments about how, among other things, flavors attract youth to initiate tobacco product use and whether and how certain flavors may help adult cigarette smokers reduce cigarette use and switch to potentially less harmful products. FDA seeks this information to inform regulatory actions FDA might take with respect to the use of flavors in noncombustible tobacco products (e.g., e-cigarettes), such as tobacco product standards and/or restrictions on the sale and distribution of noncombustible tobacco products with flavors. In response, RAI Services Company ("RAIS") respectfully submits these comments on

¹ See *Regulation of Flavors in Tobacco Products*, 83 Fed. Reg. 12294. (Mar. 21, 2018).

Potential Countervailing Effects – Illicit Trade

1. Flood of unregulated cigarettes

- Canada has not experienced surge in illicit market
- **Illicit trade** may **decrease** in high-tax jurisdictions
 - NYC is mecca for cigarette trafficking
 - ~55% of cigarette market is untaxed
 - 48% of adults smoke menthol
 - In Bronx/Harlem, ~80% of littered packs are untaxed Newports
 - Most untaxed cigarettes from VA
- Tax-driven interstate illicit market likely to shift overseas
- 4.5 billion legal menthol packs can't be replaced
- **Smaller scale illicit market likely to emerge**
- Menthol **prices may increase** given supply/demand and enforcement risks



Countering Illicit Trade Requires Money

NYC v. U.S. Postal, (E.D.N.Y.)

- PACT Act targeted cigarette trafficking
- Banned US Postal from shipping cigarettes

Allegations:

1. US Postal had a ***“non-compliant”*** list of shippers
 - Didn’t assign anyone to deal with large shipments from parties on list
2. ***“Return to Sender”*** Program
 - International shipments of illicit cigarettes were returned to the sender (often Israeli)
 - Mailed successfully when given a second chance

City of New York v. United States Postal Serv.
United States District Court for the Eastern District of New York
February 15, 2021, Decided; February 16, 2021, Filed
19-cv-5934 (BMC)

Reporter
2021 U.S. Dist. LEXIS 28144 *; ___ F. Supp. 3d ___; 2021 WL 567270

CITY OF NEW YORK, STATE OF CALIFORNIA, STATE OF ILLINOIS, STATE OF CONNECTICUT, and COMMONWEALTH OF PENNSYLVANIA, Plaintiffs,
-against-
UNITED STATES POSTAL SERVICE and LOUIS DeJOY, in his official capacity as Postmaster General, Defendants.

Judges: Brian M. Cogan, United States District Judge.

Opinion by: Brian M. Cogan

Opinion

MEMORANDUM DECISION AND ORDER

COGAN, District Judge.

The Prevent All Cigarette Trafficking Act of 2009, known as the "PACT Act," seeks to prevent cigarette traffickers from evading [*2] state and federal law by shipping cigarettes through the mail. It thus provides that the United States Postal Service "shall not accept for delivery or transmit through the mails any package that it knows or has reasonable cause to believe contains any cigarettes." 18 U.S.C. § 1716E(a)(1). Four states and the City of New York ("plaintiffs") allege that the Postal Service has not fulfilled that obligation. They have sued the Postal Service and the Postmaster General (collectively, "defendant"),¹ seeking (1) damages and injunctive relief for violations of the PACT Act, (2) a declaratory judgment that defendant has violated the Act and that "contraband cigarettes" are "contraband *per se*" under civil forfeiture statutes, and (3) a writ of mandamus compelling defendant to comply with the Act. Defendant has moved to dismiss.

I conclude that plaintiffs have stated a claim under the PACT Act and can seek a declaratory judgment that defendant has violated the Act. Yet plaintiffs cannot seek a declaratory judgment that contraband cigarettes are contraband *per se*. This claim not only lacks an actual case or controversy; plaintiffs also lack standing to bring it. Finally, I lack jurisdiction over the mandamus claim because [*3] the PACT Act provides an adequate remedy. The motion to dismiss is granted in part and denied in part.

BACKGROUND

¹Having succeeded Megan Brennan as Postmaster General, Louis DeJoy should be substituted under Federal Rule of Civil Procedure 25(d). The Clerk is directed to amend the docket sheet accordingly.

Potential Countervailing Effects – Sales to Youth

2. Increased sales to underage buyers

- Depends on size of illicit market
- Access to illicit market is likely to vary
- Fails to account for youth smoking and ECIG trends

3. Make-your-own menthols

- Flavor accessories emerging (Rizla)
 - could be regulated as “*additive*” under TCA
- DIY processes might not produce high quality menthol cigarettes
- Scale likely to be small

Imperial Tobacco adds menthol accessories to portfolio

By Éilis Cronin in Tobacco 16th December 2019

Print

Imperial Tobacco is set to launch Rizla Flavour Infusions in January 2020, in a move designed to “offer menthol shoppers a fresh new proposition that will allow them to discover great flavours and help retailers protect their sales ahead of the menthol ban next year”.



Potential Countervailing Effects – Criminalization

4. Criminalizing menthol cigarettes

- Al Sharpton (NAN) (+ **RAI \$\$\$**) attempting to manufacture a racial justice issue
- RAI's argument is **fear-based**, not evidence based
- Misrepresents enforcement strategies that typically focus on retailers

NEW YORK POST

Critics: Al Sharpton, Corey Johnson holding up menthol-cig ban

By Rich Calder

November 24, 2019 | 8:15pm

When the Rev. Al Sharpton calls, City Council Speaker Corey Johnson apparently listens.

A bill to ban menthol-cigarette sales in the city has garnered overwhelming support in the council, yet Johnson refuses to bring it to a vote on the floor — because of concerns pushed by the Rev. Al Sharpton, whose organization rakes in dough from the top-selling US menthol-cigarette manufacturer.

Sharpton and his powerful National Action Network

potentially
used by

history of
eynolds,
thol



Potential Countervailing Effects – Tax Revenue

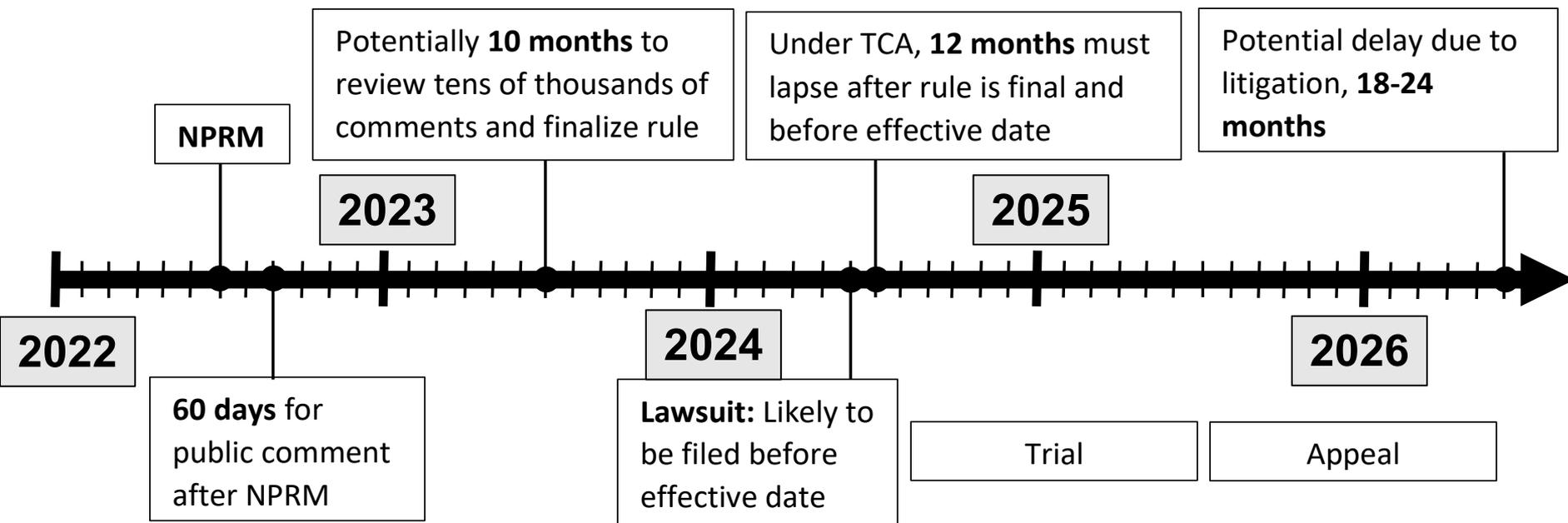
5. Loss of tax revenue

- Altria estimates **\$63 billion** is generated annually
 - Excise taxes
 - MSA payments
 - Sales tax
 - Income tax (corporate and personal from tobacco-related businesses)
- A fraction of the \$63 billion is from menthol



Cost of smoking-related illnesses is more than **five times** greater

Optimist's Timeline

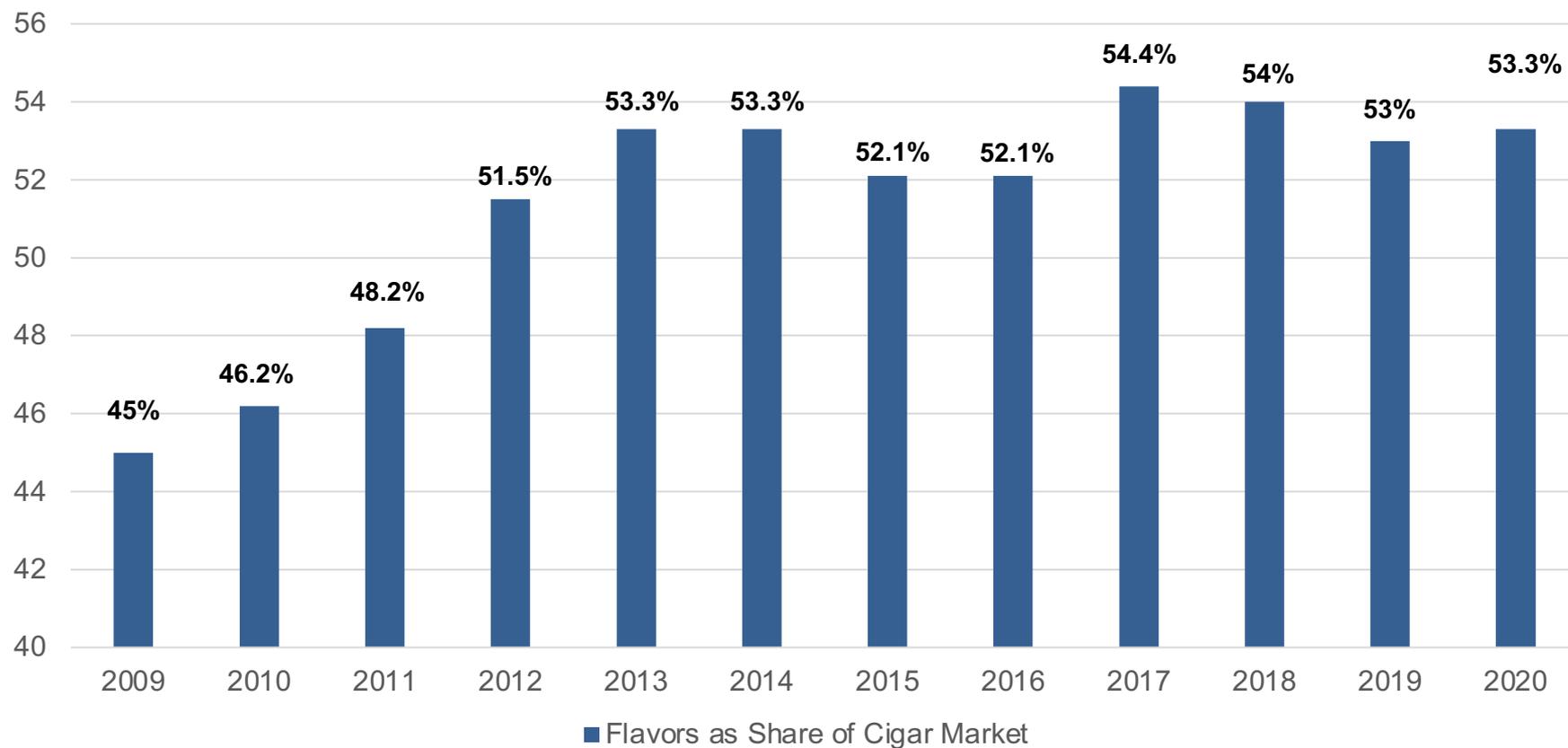


What About Flavored Cigars?



Flavored Cigars' Increasing Share of Cigar Market

Flavors as Share of Cigar Market



Convenience Stores Sales Driven by Flavored Cigars

- From 2009 to 2020 c-stores sales totals increased:
 - 32% for cigars overall
 - 56.3% for flavored cigars
- 79% of the total attributable growth in c-store cigar sales is from flavored cigars
- “In other words, flavors keep the machine-made cigar industry humming” - Cristine Delnevo, PhD, MPH

Localities Took the Lead on Flavors

Major Cities

- NYC (2009)
 - Upheld by 2nd Circuit (2013)
- Providence (2012)
 - Upheld by 1st Circuit (2013)
- Chicago (2013)
- Minneapolis (2015)
- San Francisco (2017/2018)

States

- Massachusetts (2019)
- California (2020/2022)



Recent Laws Stronger

- All retailers
- Menthol
- Flavored e-cigarettes
- (Some flavor laws solely target e-cigs)

Enforcement Challenges

Enforcement Protocols	Challenges
Product name-based enforcement	<ul style="list-style-type: none">• Concept flavors, e.g., Jazz, evade protocol• Names/colors are attractive to consumers
Lists of flavored products	<ul style="list-style-type: none">• Creating lists is burdensome• New products mean process never ends• Subject to litigation
Place burden on retailer	<ul style="list-style-type: none">• Mass. Requires retailers to get letter from manufacturer• San Fran. similar but less prescriptive

Concept Flavors Frustrate Name-Based Enforcement

Grape



Purple Thunder



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Lists of Prohibited Products Are Difficult to Manage

- *Massachusetts Association of Health Boards* (MAHB) created a list of flavored tobacco products
- Based on various sources
 - 34 pages long
 - 12 pp for cigar/cigarillo/blunt wrap
 - 15 pp for E-Cig liquids
 - 3 pp for Hookah/Shisha
 - 2 pp for pipe tobacco
 - 2 pp for smokeless

MAHB Flavored Product Guidance List Updated 12/18/2017

PRODUCT TYPE	BRAND	NAME	DATE ADDED
Cigar/Cigarillo/Blunt Wrap	1839	BLACKBERRY	10/1/2015
Cigar/Cigarillo/Blunt Wrap	1839	CHERRY	10/1/2015
Cigar/Cigarillo/Blunt Wrap	1839	VANILLA	10/1/2015
Cigar/Cigarillo/Blunt Wrap	1882	BOURBON	10/1/2015
Cigar/Cigarillo/Blunt Wrap	1882	HONEY BERRY	10/1/2015
Cigar/Cigarillo/Blunt Wrap	1882	WHITE GRAPE	10/1/2015
Cigar/Cigarillo/Blunt Wrap	38 SPECIAL	CHERRY	10/1/2015
Cigar/Cigarillo/Blunt Wrap	38 SPECIAL	GRAPE	10/1/2015
Cigar/Cigarillo/Blunt Wrap	38 SPECIAL	PEACH	10/1/2015
Cigar/Cigarillo/Blunt Wrap	38 SPECIAL	PINEAPPLE	1/5/2016
Cigar/Cigarillo/Blunt Wrap	38 SPECIAL	VANILLA	10/1/2015
Cigar/Cigarillo/Blunt Wrap	4 KINGS	APRICOT BRANDY	9/18/2017
Cigar/Cigarillo/Blunt Wrap	4 KINGS	BANANA SPLIT	8/17/2016
Cigar/Cigarillo/Blunt Wrap	4 KINGS	BLUEBERRY PINEAPPLE	9/18/2017
Cigar/Cigarillo/Blunt Wrap	4 KINGS	CRANBERRY APPLE	9/18/2017
Cigar/Cigarillo/Blunt Wrap	4 KINGS	FRENCH VANILLA	8/17/2016
Cigar/Cigarillo/Blunt Wrap	4 KINGS	GRAPE	8/17/2016
Cigar/Cigarillo/Blunt Wrap	4 KINGS	KIWI BERRY	9/18/2017
Cigar/Cigarillo/Blunt Wrap	4 KINGS	MANGO	10/1/2015
Cigar/Cigarillo/Blunt Wrap	4 KINGS	MELON BERRY	9/18/2017
Cigar/Cigarillo/Blunt Wrap	4 KINGS	MINT CHOCOLATE CHIP	8/17/2016
Cigar/Cigarillo/Blunt Wrap	4 KINGS	NAPA GRAPE	8/17/2016
Cigar/Cigarillo/Blunt Wrap	4 KINGS	PINA COLADA	8/17/2016
Cigar/Cigarillo/Blunt Wrap	4 KINGS	PUMPKIN SPICE	8/17/2016
Cigar/Cigarillo/Blunt Wrap	4 KINGS	PUMPKIN SPICE	9/18/2017
Cigar/Cigarillo/Blunt Wrap	4 KINGS	PURPLE SENSATION	9/18/2017

Enforcement Challenges

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Product name-based enforcement	<ul style="list-style-type: none">• Concept flavors, e.g., Jazz, evade protocol• Names/colors are attractive to consumers
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Mass & Manufacturer Letters

- Before selling tobacco products, retailers must secure a letter from the manufacturer
- Letter must:
 - List products at store
 - Certify they're not flavored

TO: Tobacco Product Retailers

FROM: Massachusetts Tobacco Cessation and Prevention Program

DATE: January 4, 2021

RE: Notice of guidance for the documentation of nicotine content in electronic delivery systems

Prior to the sale of any electronic nicotine delivery system (ENDS), a retailer must first obtain a letter from the manufacturer verifying its products comply with 105 CMR 655.010. The letter is intended to verify the product's nicotine content does not exceed 35 milligrams per milliliter. This letter is not required in smoking bars or adult-only tobacco retailer establishments where no one under the age of 21 is allowed to enter the premises as defined by 105 CMR 655.005. The following is required for the letter:

- The letter must be from the product manufacturer, and must list all of the manufacturer's brands, sub-brands, and brand sizes you offer for sale at your store.
- The letter must attest that each brand, sub-brand, and brand size contained in the letter does not have a nicotine content of greater than 35 milligrams per milliliter.

Please note that a retailer may not offer for sale any brand, sub-brand, or brand size not so listed in the manufacturer's letter.

What About FDA's PMTA Process?

SE Applications

- Are new cigars (post 2/15/2007) ***substantially equivalent*** to predicate cigars?
- If not, does the new product raise ***different questions of public health?***

SE Orders

- SE Orders suggest flavors are not a factor
- Toxicity matters
- No apparent analysis regarding flavors attracting more consumers

SE Orders

Applicant: Black & Mild *Jazz*

Predicate: Black & Mild *Wine*

- B&M says Jazz's flavor is "none"
- FDA is agnostic

2019 footnote in Jazz SE Order:

⁴ The applicant uses the term "identifying flavor" to indicate whether it identifies the cigar product by use of a flavor identifier. For the new product, the applicant states that the identifying flavor is "none." Properties to uniquely identify the new tobacco product were provided by the applicant, and not confirmed by FDA. In this case, FDA determined that no additional information regarding characterizing flavor was necessary to compare the new and predicate tobacco products.

Footnotes from 2020 and after

³ The applicant uses the term (b) (4)

(b) (4)

(b) (4)

In this case, FDA determined that no additional information regarding characterizing **flavor** was necessary to compare the new and predicate tobacco products.

Cigar Product Standard

- Will SE authorization factor into litigation regarding a cigar product standard?
- Who decides if a cigar is flavored?
 - FDA authorized *Jazz*
 - FDA declined to state if it's flavored
 - For years, B&M argued in MA lawsuit that Jazz is unflavored
 - Can FDA authorization play into an industry argument?

The background of the slide is a solid red color. A large, faint, circular seal of Rutgers University is centered behind the text. The seal features a sunburst in the center and the words "RUTGERS THE STATE UNIVERSITY OF NEW JERSEY" around the perimeter.

RUTGERS

THE STATE UNIVERSITY
OF NEW JERSEY

Questions?