Agenda

1. Brief recap of the Tobacco Control Act and ENDS
2. Major US ENDS and adjacent products developments since last summer’s conference.
3. Litigation update
4. What can the ENDS industry expect in 2019 - 2020?
1. Brief Recap of the Tobacco Control Act and ENDS

- Family Smoking Prevention and Tobacco Control Act (TCA) was signed into law in 2009
  - Gave FDA regulatory authority over products made and derived from tobacco (which are not drugs). Technically synthetic nicotine is not one of them.
  - Initially, TCA had jurisdiction over cigarettes, roll-your-own and smokeless (oral) tobacco
  - In 2016 FDA’s “Deeming Rule” brought all other tobacco-derived products (including ENDS) under TCA
  - Most onerous requirement is the premarket review and authorization of any new products or of modifications of existing products – i.e., of products that were not on the market on February 15, 2007 (no ENDS product qualified as of that date).
    - Cigarettes had it easy: in 2011 manufacturers had to submit a simpler product dossier (Substantial Equivalence, or SE Report) to the FDA and could continue to sell
    - Most cigarette products either were on the market in 2007 or were able to demonstrate substantial equivalence to a 2007 “predicate”
1. Brief Recap of the Tobacco Control Act and ENDS (continued)

• Deeming Rule disallowed introduction of new ENDS products or modifications of existing products after August 8, 2016
  • In reality, tens of thousands of SKUs, most produced by micro-manufacturers, were introduced since 2016. FDA enforcement still lagging, though several inquiry letters were sent to ENDS manufacturers in February 2019.

• Various aspects of the Deeming Rule were challenged on the day it was published (Nicopure Labs LLC et al. v. FDA et al.). “Nicopure” case on appeal.

• Under Deeming Rule, ENDS manufacturers had until August 2018 to submit a comprehensive product dossier (termed a Premarket Tobacco Product Application, or PMTA) to the FDA
  • 2018 deadline was extended by former commissioner Gottlieb to 2022
  • Gottlieb later announced a staggered PMTA compliance date for flavored and “underage-appealing” vs. menthol/tobacco ENDS products (2021 vs. 2022)
  • As we will discuss in detail, a recent Maryland court ruling might bring the ENDS PMTA submission deadline even closer
2. Major 2018 – 2019 FDA Developments Impacting the ENDS industry in the U.S.

Deeming Rule Deadlines for Various ENDS Compliance Requirements

• August 2018: nicotine warnings requirement came into effect on packaging and all communication. By comparison, cigarettes carry smaller warnings.
2. Major 2018 – 2019 FDA Developments Impacting the ENDS industry in the U.S.

Deeming Rule ENDS Deadlines (continued):

   Ingredients Listing (i.e., reporting ingredients to the FDA, confidentially) for small scale manufacturers not affected by natural disasters was **November 8, 2018**. For those affected by natural disasters as designated by the Federal Emergency Management Agency - extended to **May 8, 2019**.

   Harmful and potentially harmful constituents (HPHCs) submission: 6 months (9 months for small scale manufacturers) from the publication of a final guidance for existing ENDS products. 90 days before marketing for new products subject to a PMTA.
2. Major 2018 – 2019 FDA Developments Impacting the ENDS industry in the U.S.

New FDA Guidance:

PMTA Guidance (week of June 10, 2019)

2018:

“Interpretation of and Compliance Policy for Certain Label Requirement; Applicability of Certain Federal Food, Drug, and Cosmetic Act Requirements to Vape Shops”

• Clarifies what constitute modifications outside a Marketing Authorization Order (e.g., repairs and modifications of atomizer heads, refilling ENDS for a customer, assembles a product)
2. Major 2018 – 2019 FDA Developments Impacting the ENDS industry in the U.S.

New FDA Draft Guidance:

March 2019 – “Modifications to Compliance Policy for Certain Deemed Tobacco products”

FDA intends to prioritize enforcement regarding the lack of marketing authorization against:

• Flavored ENDS products (other than tobacco-flavored, mint-flavored, and menthol flavored ENDS products) that are offered for sale in ways that pose a greater risk for minors to access such products;

• Flavored ENDS products (other than tobacco-flavored, mint-flavored, and menthol flavored ENDS products) that are offered for sale in the United States after **August 8, 2021**, without the manufacturer submitting (and FDA receiving) a premarket application (or after action by FDA on that application, as described below); and/or

• All ENDS products that are targeted to minors or likely to promote use of ENDS by minors.
2. Major 2018 – 2019 Developments Impacting the ENDS industry in the U.S.

Other FDA actions:

• On September 12, 2018, FDA announced a series of actions related to the sale and marketing of ENDS products to minors, including that it had conducted nationwide, undercover investigations of brick-and-mortar and online stores over the summer of 2018 and issued more than 1,300 warning letters and CMP complaints to retailers who illegally sold ENDS products to minors.

• FDA also issued 12 warning letters to online retailers that were selling misleadingly labeled and/or advertised e-liquids resembling kid-friendly food products such as candy and cookies.

• FDA issued letters to five ENDS product manufacturers, requesting each company to submit a plan describing how it would address minors’ access to and use of its products.
2. Major 2018 – 2019 Developments Impacting the ENDS industry in the U.S.

Other FDA events:

• Commissioner Gottlieb resigned abruptly in March; interim commissioner Ned Sharpless from the National Cancer Institute appointed.

• First non-combustible cigarette PMTA authorized by FDA for Philip Morris International IQOS in April 2019.
  • This authorization provides additional clarity as to FDA high threshold of expectation for PMTAs
  • Reassuring that an order can be obtained, given sufficient time and resources (something most of the ENDS industry does not have)
  • ENDS consultants should examine the volume and complexity of information submitted in the PMTA.
3. Litigation update

1. **Nicopure et al. v. FDA et al.**: awaiting a Court of Appeals for the District of Columbia decision

   - Two commercial freedom of speech challenges to the Modified Risk/Modified Exposure Tobacco Product provision of the TCA and the ban on samples.
   - If FDA prevails, plaintiffs have an opportunity to seek a discretionary appeal before the Supreme Court.
3. Litigation update

2. American Academy of Pediatrics et al. v. FDA et al. - in 2018 several NGOs, including Truth Initiative (formerly American Legacy Foundation, or Legacy) and individual pediatricians challenged FDA’s extension of the premarket review deadline for ENDS review and argued that FDA’s guidance failed to meet the Administrative Procedure Act notice and comment requirements.

- Suprisingly, the judge found that the plaintiffs had standing to sue
- Found that FDA violated the APA and thus the PMTA deadline extension is unlawful
- Ordered plaintiffs and FDA to submit briefs within a total of 30 days describing an acceptable plan to expedite ecigarette PMTA review
3. Litigation update

American Academy of Pediatrics et al. v. FDA et al. (continued)

On May 29, 2019, plaintiffs required the judge to issue an order moving the PMTA deadline to 120 days from the judge’s final order, FDA to report on status every 90 days and request that the grace period for ENDS sell through after filing PMTA to be limited to one year, if FDA does not grant a marketing order within the year.

FDA answered asking for 10 MONTHS FOR PMTAs for ENDS and another year for review (i.e., ENDS PMTAs will be due approx. late spring 2020)

Zeller’s declarations was attached to FDA’s answer and confirmed that NO PMTAs for ENDS ARE CURRENTLY BEING REVIEWED
3. Litigation update

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

AMERICAN ACADEMY OF
PEDIATRICS, et al.,

Plaintiffs,

v.

UNITED STATES FOOD AND DRUG
ADMINISTRATION, et al.,

Defendants.

Civil Action No. 8:18-cv-883-PWG

DEFENDANTS’ REMEDY BRIEF
3. Litigation update

If the Court nevertheless enters an injunction requiring premarket applications to be submitted by a date certain, it should not adopt the 120-day deadline that Plaintiffs propose. As explained in the attached declaration of Mitchell Zeller, Director of the FDA’s Center for Tobacco Products, that precipitous deadline “would cause significant public health concerns, as well as implementation challenges.” Zeller Decl. ¶ 15. It could suddenly clear the market of thousands of e-cigarette products, raising the risk that some former smokers addicted to nicotine might migrate back to conventional cigarettes, and is likely to flood the agency with thousands of low-quality applications that would strain agency resources and significantly delay processing. Id. ¶¶ 15, 18. Thus, if the Court orders a deadline for the submission of premarket applications, it should set that deadline no sooner than 10 months from the date of its decision (with a one-year period for FDA review, without limiting the agency’s discretion to take enforcement action in the meantime). These dates, while still significantly accelerated, would at least reduce the expected abrupt and massive market exit of e-cigarette products,
To date, the FDA has received few PMTAs that meet even the basic requirements for them to be considered properly filed. As of April 30, 2019, the agency had received 401 PMTAs, 373 of which were for deemed products. Zeller Decl. ¶ 5(d). Of those 373, more than 99% (369/373) were closed as insufficient to accept or file, largely for failure to include an environmental assessment, and the manufacturers have not refiled corrected versions. Id. Overall, just 12 PMTAs have been authorized, for smokeless tobacco and noncombustible, “heated” cigarettes (which differ from e-cigarettes in that they vaporize actual tobacco, rather than an e-liquid). See id. And only 4 PMTAs remain pending for deemed products, none of them for e-cigarette products. Id. Moreover, as part of the premarket authorization process, tobacco manufacturers routinely consult with FDA, similar to the analogous process for new drug or device applications under the Federal Food, Drug, and Cosmetic Act (FDCA). See id. ¶ 5(d). Yet only a handful of manufacturers—“fewer than 10”—“have sought pre-submission meetings with FDA to discuss potential premarket applications for ENDS products.” Id. ¶ 15.
4. What can the ENDS industry expect in 2019-2020?

Standard for nicotine in cigarettes planned by FDA later this year – possibly a proposed rule
ENDS flavors continue to be scrutinized
Nicotine salts products under increased scrutiny
Interim Commissioner Sharpless not likely to take any actions in favor of the ENDS industry
The Supreme Court might be interested in a new First Amendment case if Nicopure does not prevail on appeal.
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