

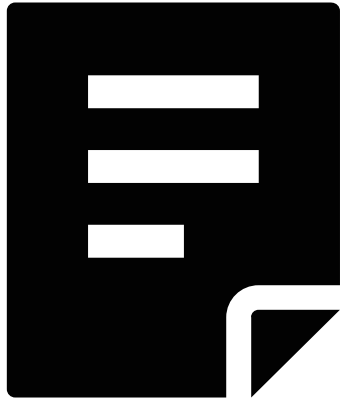
FDA Update: PMTA Program



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Received
6.7 M PMTAs
around Sept 9, 2020

RTA: Refuse To Accept
RTF: Refuse To File
MDO: Marketing Denial Order
EA: Environmental Assessment



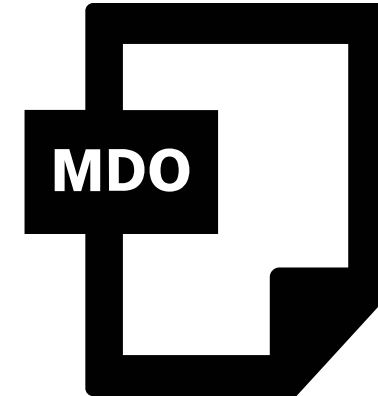
Final Actions
6.4 M

222,000 RTAs

- All product types
- Missing product-specific EAs

5.0 M RTFs

- All product types
- Lack of complete EA for every product
- Lack of complete ingredient list
- Lack of manufacturing information



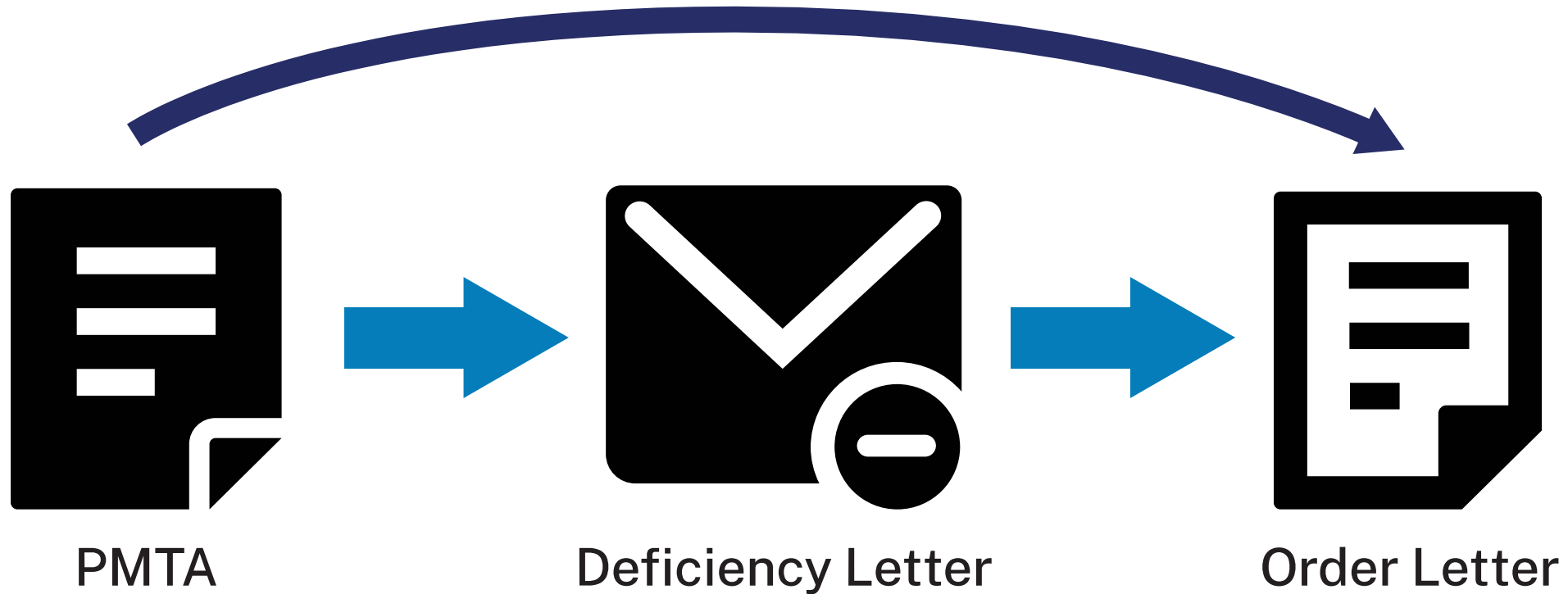
MDOs
1.2 M

Non-tobacco/non-menthol e-liquids

Lack randomized controlled trial, longitudinal cohort study, or other product-specific evidence that evaluate product switching or cigarette reduction resulting from use of the new products over time & evaluate these outcomes based on flavor type to enable comparisons between tobacco and other flavors

WHY STRAIGHT TO MDO AND NOT DEFICIENCY LETTER?

Major Data Needed for APPH Not Present



VUSE SOLO FINAL ACTIONS

- Reusable cartridge-based vapes
- Issued 3 MGOs & 10 MDOs on Oct 12
 - MGO: Vuse Solo Power Unit, Vuse Original 4.8% G1, & Vuse Original 4.8% G2
 - MDO: flavored e-liquids
- PMTAs received by Sept 9, 2020
- MGOs based, in part, on
 - Toxicity: sig lower than cigarettes
 - Abuse liability: lower than cigarettes & similar or lower than other vapes
 - Intention to use: high for cigarette smokers
 - Youth appeal: low for tobacco flavored e-liquids



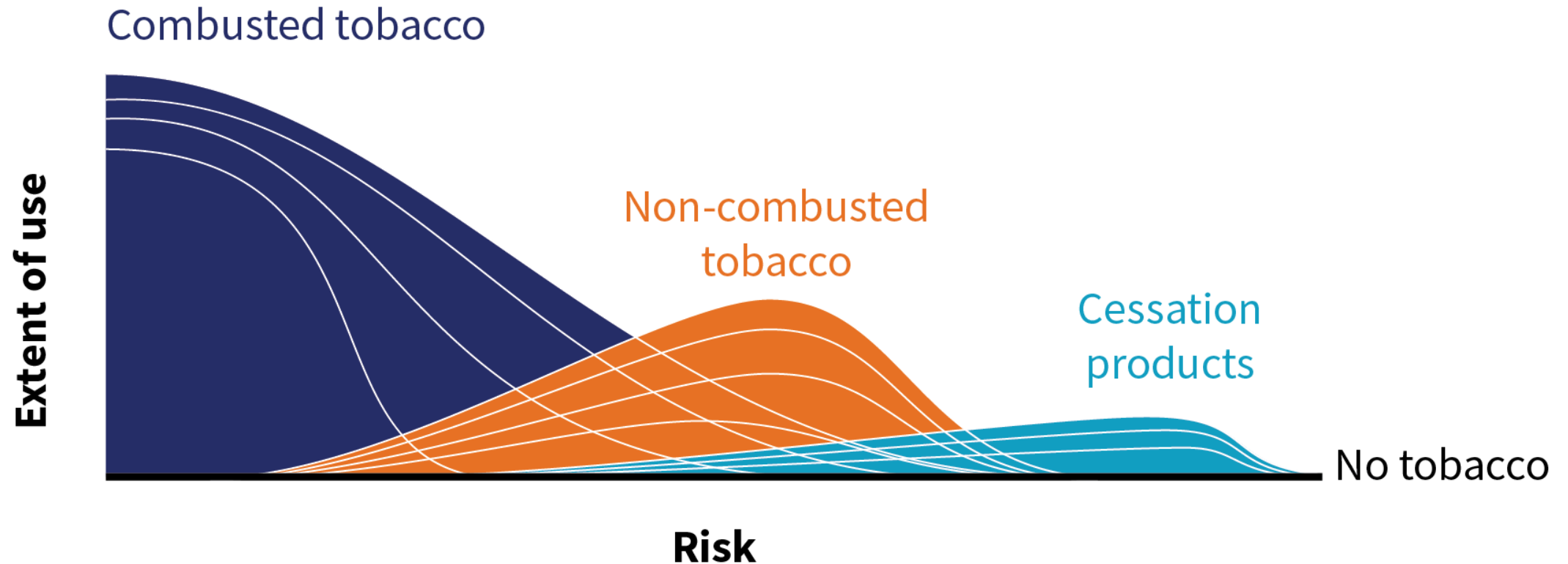
VERVE FINAL ACTIONS

- Oral tobacco products with tobacco-derived nicotine
- Issued 4 MGOs on Oct 19
 - VERVE Discs Blue Mint
 - VERVE Chews Blue Mint
 - VERVE Discs Green Mint
 - VERVE Chews Green Mint
- PMTAs received in July 2018
- MGOs based, in part, on the following data
 - Toxicity: sig lower than cigarettes & other smokeless
 - Abuse liability: lower than cigarettes
 - Intention to use: cigarette smokers & smokeless users
 - Youth appeal: low



Key Issues for APPH Determination

CONTINUUM OF RISK

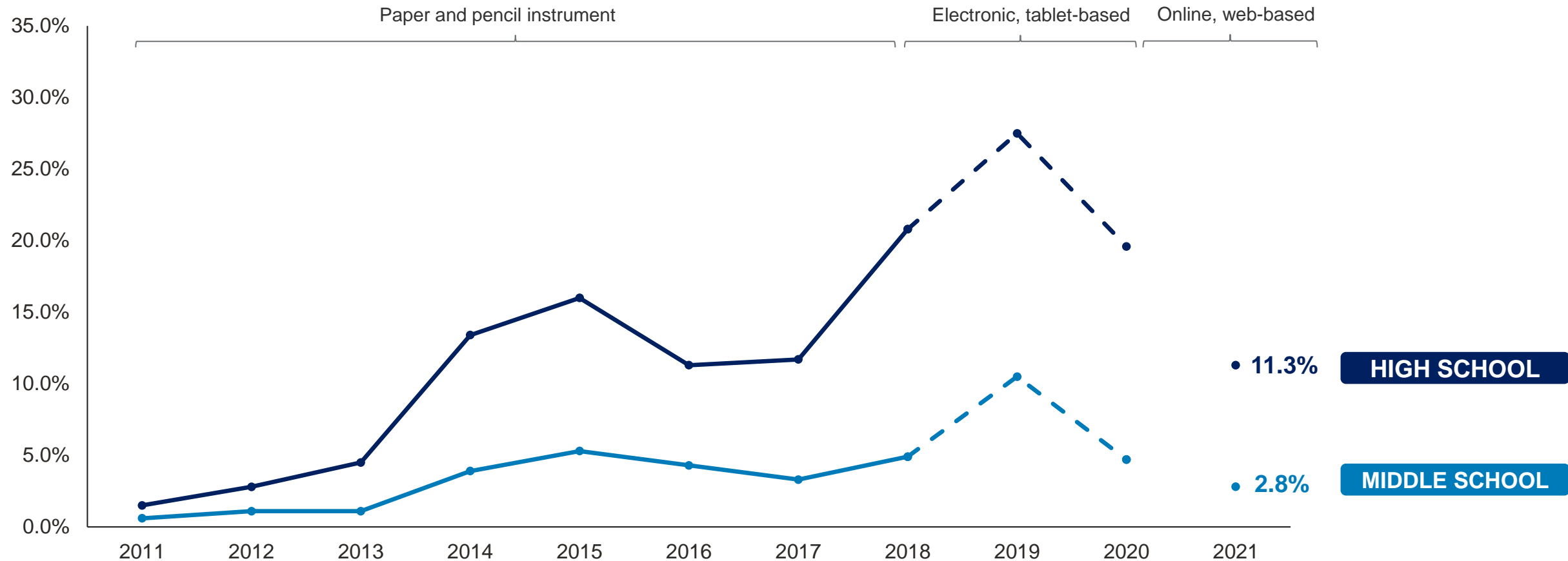


*Conceptual model, not to be interpreted as actual tobacco use data

APPH REQUIRES BALANCING YOUTH UPTAKE & SMOKER SWITCHING



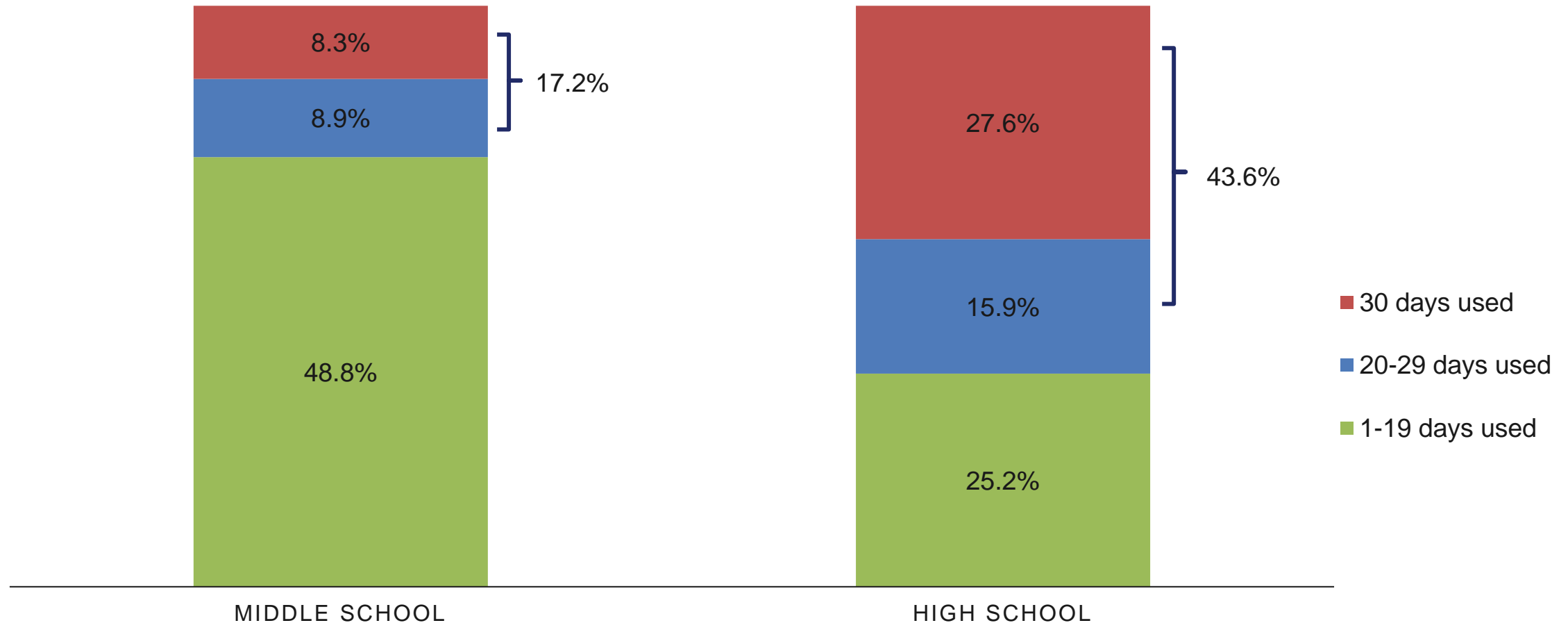
NYTS: PAST 30-DAY E-CIGARETTE USE



Data from the 2021 NYTS should not be directly compared with other years of data collection.

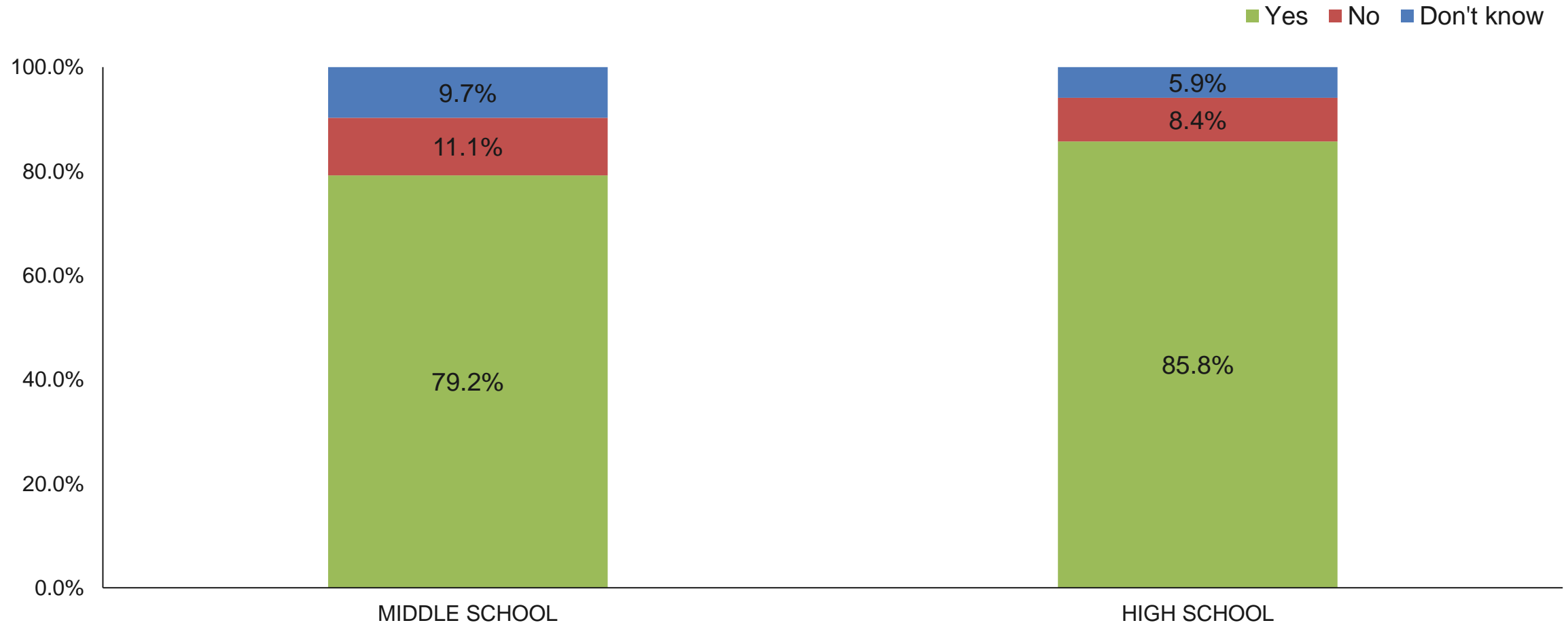
NOTE: Past 30-day use of e-cigarettes was determined by asking, "During the past 30 days, on how many days did you use e-cigarettes?" Current use was defined as use on >1 day during the past 30 days.

2021 NYTS: FREQUENCY OF E-CIGARETTE USE IN THE PAST 30 DAYS AMONG CURRENT E-CIGARETTE USERS



NOTE: Frequency of e-cigarette use was determined by asking, "During the past 30 days, on how many days did you use e-cigarettes?"
SOURCE: National Youth Tobacco Survey (NYTS), 2021.

2021 NYTS: FLAVORED E-CIGARETTE USE IN THE PAST 30 DAYS AMONG CURRENT E-CIGARETTE USERS



NOTE: Flavored e-cigarette use was assessed by the question, "Were any of the e-cigarettes that you used in the past 30 days flavored to taste like menthol, mint, clove or spice, alcohol drinks, candy, fruit, chocolate, or any other flavor?" Response were "yes," "no," or "don't know."

SOURCE: National Youth Tobacco Survey (NYTS), 2021

Marketing & access restrictions alone are inadequate



PMTA Final Rule

PMTAs must comply with the rule beginning November 4th



PMTA FINAL RULE: FILING REQUIREMENTS

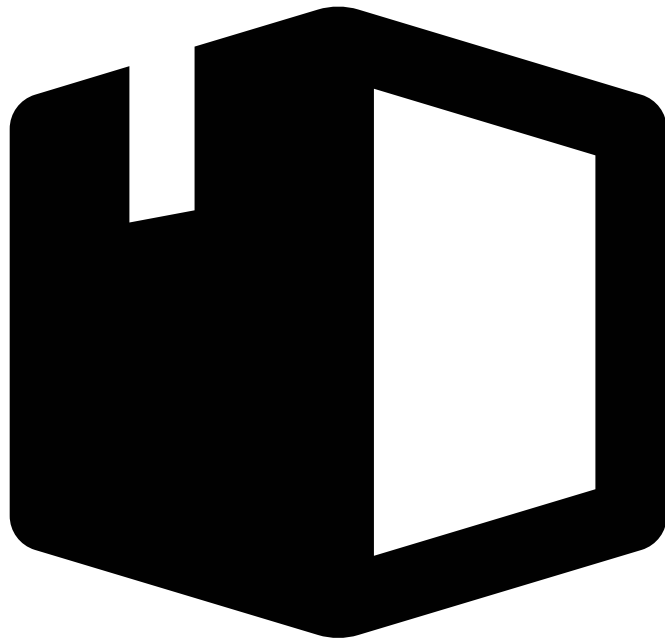
Filing = *substantive information* regarding 8 key health risk topics, including

- Health risks and comparative health risk information
- Likelihood of initiation and other changes in tobacco product use behavior
- Product perceptions and use intentions
- Human factors

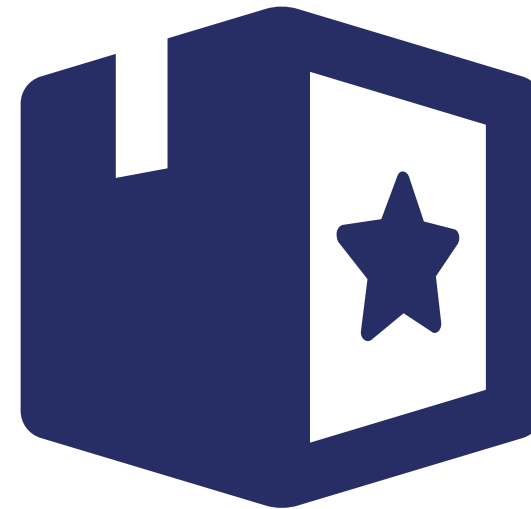
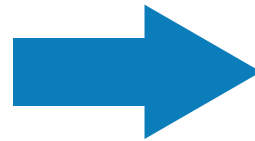


PMTA FINAL RULE: SUPPLEMENTAL PMTA

Streamlined PMTA seeking authorization for modification to a product with a PMTA authorization



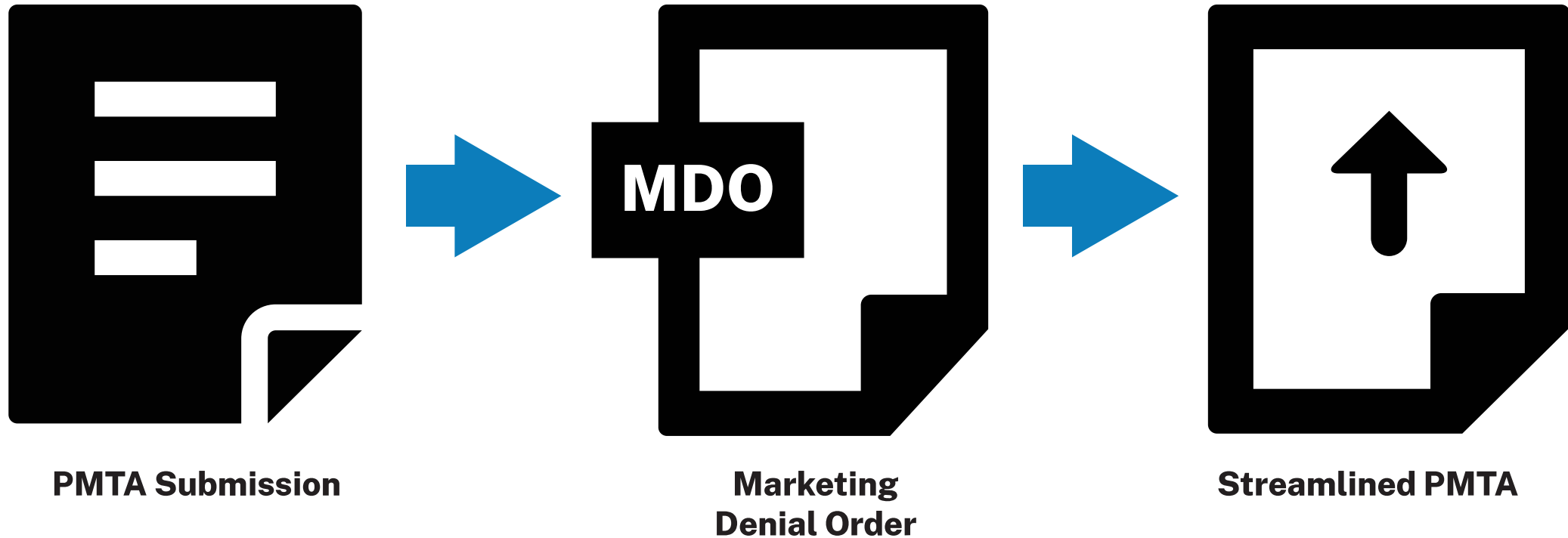
PMTA



Supplemental PMTA

PMTA FINAL RULE: RESUBMISSION

Streamlined PMTA to address deficiencies in a previously denied PMTA



PMTA FINAL RULE: MAJOR CHANGES FROM PROPOSED RULE



- Does not apply to “Premium” cigars consistent with *Cigar Ass’n v FDA* decision
- Term “grandfathered tobacco product” changed to “pre-existing tobacco product”
- Term “vulnerable populations” defined and added throughout as a point of emphasis
- Products test marketed as of Feb. 15, 2007, are now considered Pre-Existing Tobacco Products (not new products)
- Marketing plans section contains targeted requirement that focuses on key elements that directly inform APPH determinations
- Heated tobacco products (HTPs) defined as a product category

CONCLUSION

- FDA was able to take final action on nearly all PMTAs by Sept 9
- FDA still needs to make APPH determination for additional PMTAs
 - Move users down the continuum of risk
 - Balance adult smoker benefits against youth uptake risk
- PMTA final rule effective on November 4th

