Towards a More Efficient, Predictable and Transparent Premarket Review Process

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What are we trying to achieve?

"[T]he FDA plans to issue foundational rules to make the product review process more efficient, predictable, and transparent for manufacturers, while upholding the agency's public health mission." FDA News Release, July 28, 2017.

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How might that be achieved?

- Regulations regarding information expected in PMTAs and MRTPAs
- Finalizing guidance on how the FDA intends to review PMTAs
- Product standards regarding “known public health risks such as electronic nicotine delivery systems (ENDS) battery issues”
- Product standards regarding liquid nicotine exposure

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Types of Clarity

- Clarity regarding information expected in premarket review submissions
- Clarity regarding the review process
- Clarity regarding the standards for review of premarket submissions -- is there any reason we can't be more specific than "appropriate for the protection of public health"?

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Potential Sources of Clarity

- Guidance
- Regulations
- Product Standards

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Guidance

- Do not have the force of law
- Non-binding on the FDA and regulated entities
- May lack the rigor of requirements developed through notice-and-comment rulemaking
- Can be implemented relatively quickly

Regulations

- Have the force of law
- Generally have a higher level of rigor as a function of the notice-and-comment process
- Can take a long time to implement, also as a function of the notice-and-comment process

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Product Standards

- Governed by Section 907 of the Tobacco Control Act
- Standards and considerations:
  - "appropriate for the protection of the public health"
  - risks and benefits at a population level
  - Increased or decreased likelihood of initiation and cessation
- Identical to the standards and considerations for review of PMTAs as set forth in Section 910

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Product Standards

- Require notice-and-comment rulemaking
- Generally cannot take effect until a year after publication
- Additional considerations of technical achievability and potential for contraband

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Product Standards

- Have the force of law
- Have a higher level of rigor
- Will take a long time to implement
- Have the potential virtue of providing more clarity regarding the ultimate standard of review for premarket approval

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