

# **Risk Evaluation and Mitigation Strategy Public Meeting**

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# Disclosure

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Pinney Associates develops, implements and evaluates REMS for pharmaceutical developers and manufacturers. I am not appearing on behalf of any of our clients; thus the views presented here are our own.

# Key Principles

- Need a standardized process that is defined by predictability and feasibility
- Need increased transparency, including openness in discussions between industry and the FDA
- FDA should facilitate the process when requesting the development of a single-shared REMS program in order to ensure collaboration at every step in the development, implementation, and assessment process so that competition is not inhibited and the best ideas are considered

# Elements to Assure Safe Use (ETASU)

- Proposed REMS tools and elements should be demonstrated to be effective prior to asking industry to use them
- ETASU are a burden to the health care system, however it is critical the burden not be excessive
- Need for a predictable and feasible process for developing REMS with ETASU. For example...

# Predictability (1)

- Products with the same active pharmaceutical ingredient (API) and formulation should have similar REMS
  - Among 3 products with the same API and indication, 1 has an extensive REMS, while the other 2 have no or limited REMS, resulting in preferential prescribing of the less-restricted products
  - Evaluation of REMS tools and programs (e.g., need for similar assessment methods)

# Predictability (2)

- Need consistency between Guidance and decision-making
- Need a standardized process
  - Early assessments of the potential need for REMS (e.g., what are the criteria suggesting REMS might needed; need for clear guidelines to determine appropriate tools)

# Feasibility

- One size does not fit all and is not in the interest of public health nor patient safety
  - Differences among extended-release and long-acting opioid formulations (e.g., oral formulations, patch, methadone)
  - Suicidality has not been shown to be a factor for all antiepileptics
- FDA should consider how antitrust laws may impact companies and impede collaboration on REMS
  - FDA should involve relevant brand and generic companies in the development of shared REMS

# Transparency (1)

- FDA should communicate simultaneously to NDA and ANDA holders about modifications to and/or need for a REMS to assure all patients consistently receive the most current safety information whether they use a branded or generic product. For example.....

# Transparency (2)

- FDA informed ANDA holders of modifications to Medication Guides after NDA holder has submitted amendments and FDA has approved them
- Labeling changes to generic products have been delayed by as many as a few years after changes to branded product labeling updates
- FDA informed brand company several months before the generic manufacturers of the need for a REMS

# Transparency (3)

- FDA should seek input from all stakeholders to avoid overly elaborate REMS programs that inhibit competition, impact patient access, and increase healthcare costs without benefits to patient safety
- Stakeholders should be consulted regularly by the Agency as it continues to refine its approach to the REMS development and assessment process

# Summary

- Proposed REMS tools and elements should be demonstrated to be effective prior to asking industry to use them
- ETASU are a burden to the health care system, however it is critical the burden not be excessive
- Need for a predictable and feasible process for developing REMS with ETASU
- FDA should seek input from all stakeholders to avoid overly elaborate REMS programs that inhibit access, excessively burden the health care system, and/or inhibit competition