Challenges and Opportunities for Product Standards

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Authority, Actions, Inclinations

- Section 907 of the Act
- NNN in Smokeless Products proposed rule
- July 28, 2017 Announcement
- NE Journal of Medicine article

NNN in Smokeless Products Proposed Rule

- Based on the NNN level achieved by Swedish Match in its General snus products.
- In comments Swedish Match expressed support for product standards in general, for constituent based standards, and for low levels of NNN and other constituents. But had concerns.
- The opportunities:
  - Product standards approach in place of a dysfunctional SE process.
- The challenges:
  - Reducing, not adding to the regulatory burden
  - Allowing companies to build on innovation: i.e. GOTHIATEK®
  - Selecting a level; how much risk reduction will be achieved; what are the benefits?
  - Assessing the costs; impact on US tobacco growers

July 28 Announcement

- “The FDA plans to begin a public dialogue about lowering nicotine levels in combustible cigarettes to non-addictive levels through achievable products standards.”
- “For example, the FDA intends to develop product standards to protect against known public health risks…”
- “…the 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.”

NE Journal of Medicine Article

- “Act gave the FDA a regulatory tool called a tobacco product standard…Standards may be issued to set requirements related to an ingredient or constituent in a tobacco product…”
- “The statute specifically notes that such a standard may address nicotine yields, among other characteristics.”
- “The FDA will consider peer reviewed studies in proposing a maximum nicotine level.”
- “…the FDA will pursue a regulatory framework that focuses on nicotine and supports innovation to promote harm reduction.”

Opportunities

- I interpret the Announcement as an acknowledgement that the current pathways need improvement:
  - "…the FDA plans to issue foundational rules to make the product review process more efficient, predictable, and transparent …"
- The Announcement clearly indicates that product standards are a regulatory tool FDA intends to use;
- But,
  - How broadly will product standards be used (in addition to addressing nicotine levels in cigarettes)?
  - Does FDA view product standards as anther regulatory tool in addition to the pathways, or as a possible replacement (in part or whole) for a pathway that is dysfunctional?

Challenges

- Will CTP fully consider industry input?
  - Swedish Match experience meeting with OMB regarding the proposed NNN rule;
  - From the NE Journal: “The FDA will consider peer reviewed studies in proposing a maximum nicotine level.” Only peer reviewed articles? Is that reasonable given the unwillingness of many journals to publish industry funded studies?
  - PMTA evidence example.
- Can CTP reduce –not add to– the regulatory burden?
- Can CTP effectively quantify the benefits and costs associated with a product standard?
- How does the current Administration’s regulatory Executive Orders impact a product standard strategy?
- Can CTP demonstrate –through a cost-benefit approach– that a proposed product improves regulatory efficiency?