TOBACCO PRODUCT STANDARD FOR CIGARETTE NICOTINE LEVELS

Questions & Talking Points for Public Health Professionals

On March 16, 2018, the U.S. Food and Drug Administration (FDA) issued an Advance Notice of Proposed Rulemaking (ANPRM) to obtain information "for consideration in developing a tobacco product standard to set the maximum nicotine level for cigarettes."

This is the signature element of the agency's new regulatory plan for tobacco products. An aggressive product standard from the FDA rendering cigarettes non-addictive is a critical step towards eventually ending the death and disease inflicted by tobacco products.

Because this standard has such tremendous potential to drastically change the market for combustible cigarettes in the United States, public health stakeholders must engage fully in the process by presenting the evidence base for comprehensive rulemaking and encouraging the FDA to establish rules that are the most protec-

tive of the public's health. This will be a long process; the first step in that process is commenting on this ANPRM.

It is particularly important to tell the FDA that:

- The existing evidence base strongly supports FDA action to reduce nicotine in combustible products.
- Given the millions of lives at stake, the FDA needs to finalize this regulation as soon as possible.
- A comprehensive nicotine standard must address all combustible tobacco products: cigarettes, all cigars, so-called "heat-not-burn" products, waterpipe tobacco, roll-your-own tobacco, and pipe tobacco.
- The FDA should quickly implement a standard for combustible products that lowers nicotine to sub-addictive levels and also implement a standard for noncombustible products that gradually lowers nicotine to sub-addictive levels over a period of years.

Submit relevant information even if the FDA has not specifically asked for it.

Unlike a Notice of Proposed Rulemaking, which solicits comments on the language and content of a proposed rule, an ANPRM allows an agency to gather information about a topic to inform a future FDA rule. In this case, the public health community has an opportunity to shape the FDA's proposal before it is written. The FDA is gathering scientific evidence, field research, and other useful information that will assist the agency in determining the scope of a future product standard and the best way to implement and enforce such a standard. The agency's questions from the notice are compiled and categorized below. Consider answering these questions as you draft and submit your comment.

Scope of the Standard

First, the FDA proposes questions regarding the scope of a product standard for nicotine. The FDA asks should a nicotine product standard:

- Apply to just combustible cigarettes?
- Apply to other combustible products?
  - If so, which ones?
  - If so, what criteria should be used to determine this?
- Be tailored to reflect differences in combustible products?
- Apply to large (so-called "premium") cigars?

  - Considering that these are primarily used by adults and have different patterns of use from regular cigars (81 FR 28973 at 29024).
  - To that end, the FDA requests information, data, or research addressing:
    - If the standard were not applicable, whether current combustible users would migrate or begin to dual-use premium cigars.
    - If the FDA could design a premium cigar exemption that would only include products that were unlikely candidates for migration or dual use.
- Apply to waterpipe tobacco products?
  - To that end, the FDA requests, information, data, or research addressing:
    - Whether waterpipe tobacco is a likely candidate for migration or dual use.
    - The health implications or relative risk consequences for a combustible tobacco user switching to waterpipe tobacco.

Full text of the FDA's questions A(1), A(2), A(3)

Technical Achievability

The FDA also asks questions about the achievability of implementing a product standard. The FDA explains that an effective date of a final rule setting a product standard may not be less than one year after publication of the rule unless there is reason to believe an earlier date is necessary for the protection of public health. There is also a provision that if the final rule causes substantial changes to farming or growing of domestic tobacco that an effective date may not be less than two years after publication. Considering that context, the FDA asks, if a nicotine product standard is issued:

- When should the effective date be?
- What timeframe for implementation would allow adequate time for the industry to comply?
- Should that timeframe be adjusted for certain manufacturers based on the number of employees or annual revenues?
- Would a 2-year, 4-year, or 6-year timeframe be appropriate?

FDA Questions E(4)(5), E(4)(6)

Possible Countervailing Effects

The FDA asks questions about the possible countervailing effects of a nicotine tobacco product standard. If a nicotine product standard is issued:

- Should the FDA consider any additional regulatory action to address the possibility of migration to, or dual use with, other tobacco products?
- Would tobacco users seek to add liquid nicotine to their very low nicotine cigarettes (VLNC)?
  - What regulatory actions could the FDA take to prevent this? Should the FDA prohibit the sale or distribution of any tobacco product designed for that purpose or reasonably foreseeable that it would be used for that purpose?
  - How could such a provision be structured efficiently and effectively to prevent this?
  - Are there other means to consider that would prevent the supplementing of nicotine to applicable products?
- Would this action affect the current illicit trade market, and if so, to what extent?
  - How would users obtain their sources of tobacco in an illicit market?
  - How would manufacturers distribute their illicit products and develop consumer awareness of such products?
  - How would such sales take place?
- Are there data that would address the likely outcomes in the following list or is there another outcome that could occur?
  - Current combustible users could continue to smoke but use the low nicotine products
  - Current combustible users could completely switch to, or dual use low nicotine products with, other legal tobacco or nicotine products
  - Current combustible users could quit using any nicotine or tobacco product
  - Current combustible users could seek to buy illegal cigarettes in an illicit market.
- And if an illicit market developed,
  - What percentage of current users would switch to illicit conventional cigarettes rather than quitting or switching to other legal products?
    - How would this change:
- If illicit conventional cigarettes were more expensive and/or harder to obtain?
- With the implementation of improved monitoring and enhanced enforcement by the FDA and its partners?
  - How long would it likely last — for example, would demand likely decrease over time, stay the same, or increase?
  - Would this have an effect on the market for illegal drugs and is there data showing a relationship between illicit tobacco use and illegal drug use?

- What mechanisms may be used to prevent, control, or contain illicit markets?
  - What State and Federal entities may be responsible for these mechanisms?
  - At what cost?

FDA Questions F(1), F(2), F(3), F(5), F(6), F(7), F(8), F(9)

Economic Impact of Regulations

Finally, the FDA asks if there are any relevant comments or information that would be helpful for the FDA to consider in analyzing the economic impacts of a proposed nicotine tobacco product standard?

FDA Question G(9)

Public health professionals preparing comments can reference the Public Health Law Center's publications *Getting Scientific Research to the FDA* and *Telling the Public Health Story to the FDA*.

Visit the Public Health Law Center's FDA Action Center for the latest developments related to the FDA's regulation of tobacco products, including additional information on the nicotine ANPRM.

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