Possible Additional Provisions for an FDA Nicotine-Reduction Rule
to Maximize Public Health Benefits
5/16/19 Draft

This memo means to continue moving us toward developing a pre-meeting group consensus regarding what elements or provisions an FDA nicotine-reduction rule should include to increase the likelihood and size of its public health gains and identify any provisions that require further discussion. Doing that will provide a solid context or foundation for the discussion at the June 12 meeting regarding how else the rule might be modified, within legal constraints, to maximize public health gains and be as ethically appropriate as possible, and regarding what additional complementary regulatory, educational, or other actions FDA might take to promote those same goals.

Previously Circulated Draft Core Elements of FDA Nicotine-Reduction Rule

- To maximize public health gains, the nicotine-reduction rule should apply to all smoked tobacco products or at least to all cigarettes (including RYO) and to all other tobacco or tobacco products that are similarly smoked or could be smoked as cigarette substitutes.[1]
- To reduce nicotine availability most effectively, the nicotine-reduction rule should set maximum amounts of nicotine allowed in the subject smoked tobacco products' tobacco, by weight, and in the product as a whole, and should not allow any nicotine in any of the non-tobacco elements of the products.
- To ensure minimum nicotine delivery, the nicotine rule should set the maximum nicotine amounts at the lowest levels that are currently technically achievable using available procedures or technologies – e.g., to 0.4 mg/gm or lower for nicotine content and 0.03 mg or lower for nicotine yields (but without going to zero for yields, which is prohibited by the TCA).
- To maximize public health gains, the new nicotine limits should go into effect on an established effective date, and not be gradually phased in through gradual step-by-step reductions over time.

Possible Additional Provisions:

The following lists some significant problems a nicotine-reduction rule might encounter that could reduce its beneficial public health impacts and then identifies some possible ways the rule, itself, might address those problems. How else these problems might be addressed will be considered later.

1. Possible Problem: Tobacco companies figure out ways to make cigarettes able to create and sustain addiction despite compliance with the nicotine-content limits.

   Existing obstacles:

   - Rule will set very-low limit on amount of nicotine allowed in cigarettes and other smoked tobacco products making it very difficult to add other ingredients or otherwise redesign the products to deliver addiction -sustaining or addiction-creating levels of nicotine.

[1] Possible non-health reason to excluding premium cigars: Would avoid potentially powerful and distracting opposition from premium cigar industry (and from politicians who smoke premium cigars), or at least substantially reduce its fervor. In addition, expensive, bona fide premium cigars (e.g., wrapped in whole tobacco leaf with no filter) cannot be deeply inhaled when smoked, like cigarettes, and could not otherwise serve as daily-use substitutes for full-nicotine cigarettes (except, perhaps, among the wealthy). But excluding premium cigars would reduce overall health gains from the rule.

- Besides nicotine, there do not appear to be any other addictive or potentially addictive constituents in smoked tobacco products in levels high enough to create or sustain physical addiction.

- TCA requires manufacturers to obtain prior permission from FDA before making any substantial changes to cigarettes or other smoked tobacco products (e.g., adding in new addictive ingredients or new additives to deliver remaining nicotine more strongly).

A. Additional rule-based obstacles needed? If not, might it still be worth including additional obstacles that are readily available and not too complicated or costly to implement?

B. Possible additional obstacles to include in the rule.
[Any legal or public-health reason not to include any or all of the following?]
[Any measure clearly unnecessary or overkill, or become so if other measures implemented?]

(1) Include more comprehensive definition of "nicotine" or "ingredients subject to limits" in the rule.

- Existing TCA definition: "The term 'nicotine' means the chemical substance named 3-(1-Methyl-2-pyrrolidinyl) pyridine or C[10]H[14]N[2], including any salt or complex of nicotine."

(a) Could add something like: "and also includes any nicotine analogues or other drugs that bind with high affinity and act on nicotinic cholinergic receptors in the central nervous system." *Anything else to include in "nicotine" or "ingredients subject to limits" definitions?*

(2) Include one or more of the following prohibitions:

(a) No tobacco product subject to this rule's nicotine limit may include any synthetic nicotine or synthetic nicotine analogue. [Apply to all tobacco products subject to TCA?]

(b) Other than ingredients or constituents in tobacco, no tobacco product subject to this rule's nicotine limit may include any additive that is nicotine or a nicotine analogue or that is intended, expected, or likely to make the product more physically or psychologically addictive, increase its potential to sustain addiction or establish or sustain physical or psychological dependence, or to establish or increase abuse potential or abuse liability among users.

(c) No tobacco in any tobacco product subject to this rule's nicotine limit may include any nicotine analogues or other potentially addictive ingredients or constituents in any amounts in excess of the higher of those levels typically found in such tobacco products prior to the implementation of this rule or those levels found in the tobacco of the lowest-nicotine Spectrum cigarettes that have been produced for NIDA for research purposes.

(3) Include one or more of the following restrictions on procedures/technologies used to reduce nicotine levels to comply with the rule:

(a) No changes to tobacco products currently legally sold in the United States shall be made to comply with this rule's nicotine limit other than those that necessarily occur because of the procedures or technologies employed to reduce the levels of nicotine in the tobacco used in the tobacco product and make the tobacco product compliant with this rule.

(b) The procedures or technologies employed to reduce the levels of nicotine in the tobacco used in a tobacco product subject to this rule's nicotine limit shall not be designed or implemented to make any changes to the tobacco or tobacco product other than those necessary to make the tobacco product compliant with this rule.

(c) Any procedures or technologies employed to reduce the levels of nicotine in the tobacco used in a tobacco product subject to this rule's nicotine limit shall be designed and implemented to prevent or minimize any increases (or maximize decreases) in the levels of any tobacco or tobacco product constituents -- such as nicotine analogues, norhamane, or certain alkaloids or aldehydes -- that are or could be physically addicting.

(4) Include limit on nicotine yields permitted by the rule, as measured by specified machine-testing procedures -- at some level clearly above what should be possible given rule's content limits (so compliance with content limit should readily ensure compliance with yield limit) but sharply lower than what cigarettes and other smoked tobacco products currently deliver.

(5) Include limit on the subject tobacco products' abuse liability -- e.g., based on Center for Drug Enforcement and Research (CDER), FDA, "Assessment of Abuse Potential of Drugs – Guidance for Industry." [Could clear measurable/testable limit be articulated in the rule?]

2. <u>Possible Problem: Consumers (with guidance from commercial entities) figure out ways to add nicotine into compliant cigarettes or compliant RYO or pipe tobacco, or figure out ways to make tobacco products not subject to rule able to be smoked like cigarettes.</u>

- Complexity, mess, inconvenience already makes adding nicotine into cigarettes impractical or unlikely?

A. Additional rule-based obstacles needed? If not, might it still be worth including additional obstacles that are readily available and not too complicated or costly to implement?

B. Possible additional obstacles to include in the rule.
[Any legal or public-health reason not to include any or all of the following?]
[Any become clearly unnecessary overkill or redundant if other, simpler ones implemented?]

(1) Prohibit the sale of any products containing nicotine or sold in conjunction with nicotine that are labeled, advertised, sold, intended, or expected to be used to boost the nicotine levels in post-rule minimum-nicotine cigarettes or other subject tobacco products (or in any other products intended or expected for human consumption).

(2) Prohibit the sale of any products labeled, advertised, sold, intended, or expected to be used to: (a) enable non-combustible tobacco products to be consumed through combustion; (b) enable any combusted tobacco products not subject to the rule to be smoked like a cigarette, including, but not limited to, any products to enable premium cigars to be smoked through a filter or to repurpose or repackage premium cigar tobacco into rolls of tobacco for smoking that are not large premium cigars.[2]

3. <u>Possible Problem: A new illicit trade in full-nicotine cigarettes emerges in response to the rule via: (a) illicit Internet sales; and/or (b) illicit on-the-ground sales.</u>

[2] Could be regulated through FDA's TCA authority to regulate any "component, part, or accessory of a tobacco product." Sec. 101(a) and 21 USC 321 (rr)(1).

Existing obstacles:

- Pharmaceutical companies selling NRTS and cessation drugs will be doing all they can to take advantage of this rule's implementation to increase sales and use, thereby prompting more smokers to quit instead of going to illicit trade.
- Companies that sell e-cigarettes, IQOS, and other full-nicotine tobacco products not subject to the rule will be pushing hard to get smokers to move to their products instead of quitting all use, further reducing demand for illicit trade.[3]
- The vast majority of smokers want to quit and many will try to do so instead of trying to find illicit full-nicotine products to smoke.
- But this a big industry argument; so any readily available, effective obstacles to increased illicit trade should probably be included in the rule even if they were not really needed.

A. Possible additional obstacles to include in the rule.
[Any legal or public-health reason not to include any or all of the following?]
[Any become clearly unnecessary overkill or redundant if other, simpler ones implemented?]

(1) To prevent the emergence of any illicit domestic manufacturing of non-compliant tobacco products, include prohibitions on the importation or domestic purchase or sale of the following items except in small, personal use amounts, for export, for the manufacture of tobacco products for export, or for the manufacture of cigarettes or other tobacco products for domestic sale by manufacturers that are registered with FDA and are otherwise in compliance with the TCA and related rules:

(a) Cigarette filters or cigarette-like filters.[4]

(b) Paper or other wrapper (other than tobacco leaf) intended or expected to be used for creating rolls of tobacco for smoking.[5]

(c) Tobacco leaf, other loose tobacco, or mixtures containing tobacco intended or expected to be used as filler or wrapper in any cigarette or other smoked tobacco product (except for importation, purchases, or sales of tobacco leaf by tobacco producers as tobacco producers).[6]

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[3] These tobacco company efforts to encourage switching (and reduce total cessation) will also reduce the public health gains from the rule. See Problem 7, below. It is possible that the TCA's MRTP provisions would not impede company efforts to urge smokers to switch to *full-nicotine* e-cigarettes or smokeless products, claiming that they would better satisfy smokers existing addictions or desire for nicotine, because those would be neither reduced-risk or reduced-exposure claims (but, rather, just increased-exposure claims). But they could not encourage switching to less-harmful or fewer-toxin e-cigarettes or smokeless from the new reduced-nicotine smoked products without a permissive MRTP order.

[4] Could be regulated through FDA's TCA authority to regulate any "component, part, or accessory of a tobacco product." Sec. 101(a) and 21 USC 321 (rr)(1).

[5] Exclusion of unprocessed tobacco leaf meant to ensure compliance with TCA Sec. 901(c)(2)(C): "The provisions of this chapter shall not apply to tobacco leaf that is not in the possession of a manufacturer of tobacco products, or to the producers of tobacco leaf, including tobacco growers, tobacco warehouses, and tobacco grower cooperatives."

[6] Exception for tobacco producers (unless they are acting as processors or manufacturers) means to ensure compliance with Sec. 901(c)(2)(C). Manufacturers could still be prohibited from buying tobacco

(2) To dampen illicit Internet sales of non-compliant smoked tobacco products, include restrictions and requirements (to the extent legally possible under the TCA) on the Internet or other remote or mail order sale or delivery of all types of tobacco products subject to the rule (paralleling the provisions of the federal PACT Act, which regulates Internet sales and deliveries only for cigarettes, cigarette RYO, and smokeless). [Could also encourage Congress to extend the PACT Act's provisions (especially those FDA cannot legally implement on its own, such as restrictions on the Postal Service) to all smoked tobacco products of the types subject to the rule.]

(3) Restrict sale of all types of smoked tobacco products subject to the rule to adult-only facilities (so that any found sold anywhere else are clearly illegal with no further testing required).

(4) Not clear whether FDA has authority: Restrict or track/trace purchases and sales of machines used for manufacturing cigarettes or other smoked tobacco products (to prevent their sale to illicit manufacturers).[7]

(5) Any other helpful provisions that might be included in the nicotine-reduction rule, itself, to prevent illicit trade or facilitate enforcement against it?

4. <u>Possible Problems: Manufacturers stockpiling before deadline for no longer manufacturing full-nicotine smoked tobacco products and consumers stockpiling before legal sales of full-nicotine smoked tobacco products end.</u>

- No existing obstacles.

A. Possible obstacles to include in the rule.
[Any legal or public-health reason not to include any or all of the following?]
[Any clearly unnecessary or overkill?]

(1) Have consecutive deadlines for stopping full-nicotine manufacturing, delivery to distributors, delivery to retailers, and retail sales to consumers that impede massive stockpiling (e.g., do not allow deliveries or sales for as long as inventories last).

(2) Prohibit cigarette sales to consumers of more than one carton per transaction or store visit in month prior to deadline for legal retail sales of full-nicotine cigarettes (with similar limits for other smoked tobacco products subject to rule).

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leaf from tobacco producers, except for permitted purposes (but under 901(c)(2)(C) an employee of the FDA would not have "any authority to enter onto a farm owned by a producer of tobacco leaf without the written consent of such producer" to enforce any such manufacturer purchase restriction.

[7] FDA might have the authority to regulate the purchase and sale of cigarette-making machines through its authorities to regulate the manufacture and distribution of tobacco products and to take action relating to misbranded products and illicit trade in tobacco products. See, e.g., Sec. (e)(1)(A) [referring to FDA "applying manufacturing restrictions to tobacco;" Sec. 903(a)(6); and Title III re illicit trade. Implementing such restrictions through an FDA rule would also be "appropriate for the protection of the public health." But if FDA determined that it did not have the authority to implement these restrictions directly, FDA could work to get them implemented via Congressional action. See, e.g., Sec. 202 of H.R. 729, 115th Congress. And legal tobacco companies might support such legislation to prevent illicit competition. Any new restrictions could include an exception for purchases and sales of the machines when they will be scrapped and when sold to museums and other bona fide non-commercial entities.

5. Possible Problem: New belief among smokers, youth, etc. that the reduced-nicotine cigarettes are not only not addictive but much less harmful than previous full-nicotine cigarettes – thereby reducing desire/intentions to quit and increasing experimentation.

   Existing obstacles:

   - Products will not be able to sustain or create physical addition to nicotine, making continued sustained use by smokers and any new initiation into regular use much less likely.
   - Cigarettes will have new graphic health warnings pursuant to new rule the court has ordered FDA to issue by March 2020. Other smoked tobacco products have non-graphic warning label requirements. [And we can assume that the warnings that warn about nicotine/addiction will no longer be required.]
   - Manufacturers could not label or advertise as "nicotine free," "99.5% nicotine free," and the like without first obtaining a permissive FDA MRTP order to allow such reduced-exposure claims.

   A. Additional rule-based obstacles needed? If not, might it still be worth including additional obstacles that are readily available and not too complicated or costly to implement?

   B. Possible additional obstacles to include in the rule.
   [Any legal or public-health reason not to include any or all of the following?]
   [Any clearly unnecessary or overkill?]

      (1) Ban menthol and all other flavors for tobacco products subject to the nicotine-minimization rule to make even less attractive for continuing use or initiation.

      (2) Do not require (or allow other than via MRTP order) any labeling of subject products or their advertising re reduced nicotine levels – or, alternatively, require labeling or product inserts/onserts re products having reduced nicotine/addiction but still just as harmful as before.

      (3) *Any other relatively simply provisions that might be included in the nicotine-reduction rule, itself, to prevent perceptions that minimal-nicotine cigarettes, etc. are considerably less harmful or to prevent related continued use or experimentation?* [We will discuss possible rule-related FDA public education efforts later.]

6. Possible Problem: Smoker demand for cessation assistance and other medical attention after the rule is implemented, or inability to address addiction through smoking, overwhelms or overburdens health care system, cessation assistance networks, or supply of cessation aids.

   Existing obstacles:

   - Pharmaceutical companies selling NRTS and cessation drugs will be doing all they can to take advantage of this rule's implementation to increase sales and use of their products, including building up their inventories beforehand.
   - Companies that sell e-cigarettes, IQOS, and other full-nicotine tobacco products not subject to the rule will be pushing hard to get smokers to move to their products instead of quitting all use, including building up their inventories beforehand, thereby reducing the number who try to quit (or who suffer from smoking that no longer feeds their addictions) and reducing any related demand for cessation assistance or related health care.[8]

[8] See item Problem 7, below.

A. Additional rule-based obstacles needed? If not, might it still be worth including additional obstacles that are readily available and not too complicated or costly to implement?

B. Possible additional obstacles to include in the rule.

(1) *Any ideas?*

7. Companies that sell full-nicotine tobacco products not subject to the rule will be pushing hard to get smokers to move to their products instead of quitting all use, thereby reducing the number who try to quit or successfully do so.

Existing Obstacles:

- Companies could not encourage switching to less-harmful or fewer-toxin e-cigarettes or smokeless from the new reduced-nicotine smoked products without first securing a permissive MRTP order (but might be able to encourage switching to more-nicotine, better-addiction-feeding or more-satisfying e-cigs/smokeless without MRTP).
- These company efforts to encourage could be beneficial if needed to reduce smoker demand for illicit full-nicotine smoked tobacco products or to prevent cessation-assistance networks from being overwhelmed in harm-increasing ways. [*Would likely health benefits be larger than health harms from reducing total cessation?*]

A. Additional rule-based obstacles needed? If not, might it still be worth including additional obstacles that are readily available and not too complicated or costly to implement?

B. Possible additional obstacles to include in the rule.
[Any legal or public-health reason not to include any or all of the following?]
[Any measure clearly unnecessary or overkill, or become so if other measures implemented?]

(1) Make e-cigarettes and smokeless less attractive (e.g., ban flavors) or less readily available (e.g., adult-only stores only).

(2) Restrict advertising of e-cigarettes and smokeless (within 1st Amendment constraints)

8. Any other possible nicotine-reduction rule problems that need to be considered?

All comments, questions, and suggestions welcome:

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