Public Interest Comment\(^1\) on
The Food and Drug Administration’s Proposed Rule:
Deeming Tobacco Products to be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products
Docket ID No. FDA-2014-N-0189
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The George Washington University Regulatory Studies Center
Retrospective Review Comment Project

The George Washington University Regulatory Studies Center strives to improve regulatory policy through research, education, and outreach. As part of its mission, the Center conducts careful and independent analyses to assess rulemaking proposals from the perspective of the public interest. This comment on the Food and Drug Administration’s proposed rule does not represent the views of any particular affected party or special interest, but is designed to evaluate whether FDA’s proposal incorporates plans for retrospective review, pursuant to Executive Order 13563.

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1 This comment reflects the views of the author, and does not represent an official position of the GW Regulatory Studies Center or the George Washington University. The Center’s policy on research integrity is available at http://regulatorystudies.columbian.gwu.edu/policy-research-integrity.

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Introduction

1. Summary of the Rule

Under authority of the Tobacco Control Act, FDA currently regulates under chapter IX of the Food, Drug, Cosmetic Act (FD&C Act) cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco. The regulation that FDA hereby sets forth proposes to deem additional products as meeting the statutory definition of “tobacco product,” and thus subject to the FD&C Act. The proposed rule consists of two co-proposals. Option 1 would deem all products meeting the statutory definition of “tobacco product” in section 201 (rr) of the FD&C Act to be subject to chapter IX of the FD&C Act. Under this scenario, the proposed rule would uniformly apply requirements—such as establishment registration, product and ingredient listing, pre-market clearance, labeling norms, and free sampling prohibition—to all tobacco products. Additional access provisions would also apply, including a minimum age requirement, limit on sales by vending machines, as well as required health and addiction warning statements on both packages and advertisements. Under this option, all “tobacco products” would be deemed subject to the FD&C Act, including all types of cigars, pipe tobacco, hookah, e-cigarettes, and novel products such as gels and dissolvable tobacco products.

Option 2 is very similar to option 1 except that it would exclude ‘premium cigars’ from coverage and would thus exempt this specific class of cigars from both the statutory restrictions under chapter IX of the FD&C Act and from the additional access provisions. The proposed rule defines ‘premium cigars’ as those that are wrapped in whole tobacco leaf, contain primarily long filler tobacco, are made of 100% leaf tobacco binder, and are manufactured manually with no filter, tip, or non-tobacco mouthpiece. Such cigars do not have a special flavor other than tobacco, their price exceeds $10 per unit and they weigh more than 6 lbs per thousand units.

FDA notes that the proposed rule is an “‘enabling regulation,” which “in addition to directly applying the substantive requirements of chapter IX of the FD&C Act and its implementing regulations to proposed deemed tobacco products, … enables FDA to issue further public health regulations related to such products.”

Based upon its impact analysis, FDA believes that the proposed rule would be an economically significant regulatory action as defined by Executive Order 12866 and further that the proposed rule would have a significant economic impact on a substantial number of small entities. The primary estimate for the upfront cost of option 1 amounts to $171.1 million. Costs in subsequent years are estimated at $30.6 million. FDA anticipates that the costs will be primarily borne by

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3 FDA explains in the preamble: “We expect that asserting our authority over these tobacco products will enable us to propose further regulatory action in the future as appropriate…” 79 FR 23196
manufacturers and importers, and that a portion of these costs will be passed on to consumers through price increases.

As part of its ongoing Retrospective Review Comment Project, the Regulatory Studies Center examines significant proposed regulations to assess whether agencies propose retrospective review as a part of their regulations, and submits comments to provide suggestions on how best to incorporate plans for retrospective review into their proposals. To facilitate meaningful retrospective review after the promulgation of a final rule, multiple government guidelines instruct agencies to incorporate retrospective review plans into their proposals during the rulemaking process.

2. Incorporating Retrospective Review into NPRMs

Through a series of Executive Orders, President Obama has encouraged federal regulatory agencies to review existing regulations “that may be outmoded, ineffective, insufficient, or excessively burdensome, and to modify, streamline, expand, or repeal them in accordance with what has been learned.” On January 18, 2011, President Obama signed Executive Order 13563, Improving Regulation and Regulatory Review, which reaffirmed the regulatory principles and structures outlined in EO 12866. In addition to the regulatory philosophy laid out in EO 12866, EO 13563 instructs agencies to consider how best to promote retrospective analysis of rules that may be outmoded, ineffective, insufficient, or excessively burdensome, and to modify, streamline, expand, or repeal them in accordance with what has been learned. Such retrospective analyses, including supporting data, should be released online whenever possible.4

This ex-post review makes it possible for the government and the public to measure whether a particular rule has had its intended effect. In his implementing memo on retrospective review, former Administrator of the Office of Information and Regulatory Affairs, Cass Sunstein, stated the importance of designing regulations to facilitate their evaluation:

With its emphasis on “periodic review of existing significant regulations,” Executive Order 13563 recognizes the importance of maintaining a consistent culture of retrospective review and analysis throughout the executive branch. To promote that culture, future regulations should be designed and written in ways that facilitate evaluation of their consequences and thus promote retrospective analyses and measurement of “actual results.” To the extent permitted by law, agencies should therefore give careful consideration to how best to promote

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empirical testing of the effects of rules both in advance and retrospectively.\textsuperscript{5} [Emphasis added]

This emphasis is repeated in Sunstein’s June 14, 2011 memo, “Final Plans for Retrospective Analysis of Existing Rules.” In its 2013 Report to Congress on the Benefits and Costs of Federal Regulations, the Office of Management and Budget (OMB) states that such retrospective analysis can serve as an important corrective mechanism to the flaws of ex ante analyses. According to that report, the result of systematic retrospective review of regulations:

should be a greatly improved understanding of the accuracy of prospective analyses, as well as corrections to rules as a result of ex post evaluations. A large priority is the development of methods (perhaps including not merely before-and-after accounts but also randomized trials, to the extent feasible and consistent with law) to obtain a clear sense of the effects of rules. In addition, and importantly, \textit{rules should be written and designed, in advance, so as to facilitate retrospective analysis of their effects}.\textsuperscript{6}

\textbf{Retrospective Review Requirements}

To evaluate whether FDA’s proposal was “designed and written in ways that facilitate evaluation of [its] consequences,” we measure it against six criteria:

- Did FDA clearly identify the problem(s) that its proposed rule is intended to solve?
- Did FDA clearly lay out how the proposed rule is intended to solve the identified problem(s)?
- Did FDA provide clear, measurable metrics that reviewers can use to evaluate whether the regulation achieves its policy goals?
- Did FDA commit to collecting information to assess whether its measurable metrics are being reached?
- Did FDA provide a clear timeframe for the accomplishment of its stated metrics and the collection of information to support its findings?
- Did FDA write its proposal to allow measurement of both outputs and outcomes to enable review of whether the standards directly result in the outcomes that FDA intends?


\textsuperscript{6} \textit{2013 Report to Congress on the Benefits and Costs of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities} (May 2014)
1. Identifying the Problem

The first of the “Principles of Regulation” outlined by President Clinton in EO 12866 makes it clear that, as a first step, agencies must be able to identify the problem that justifies government action through regulation:

Each agency shall identify the problem that it intends to address (including, where applicable, the failures of private markets or public institutions that warrant new agency action) as well as assess the significance of that problem.

This step is crucial to the formulation of any policy. Without knowledge of the problem that the agency is trying to address, the public cannot assess whether the policy or regulation at hand has had the intended effect, which is key in retrospectively evaluating regulation.

1a. Scope of the Problem

The problem that the agency is trying to address through this proposed rule is multifaceted. It is stated explicitly but in rather general terms:

In recent years new types of tobacco products, sometimes referred to as “novel tobacco products,” have become an increasing concern to public health due, in part, to their appeal to youth and young adults.7

While the overall problem is identified and characterized in terms of public health risk linked to the consumption of tobacco products, FDA further articulates three key factors justifying the need for regulating these novel tobacco products under the FD&C Act:

(i) *The addictive nature of the products, especially among youth and young adults.*8

FDA emphasizes that while little is currently known about the health consequences of novel tobacco products, they all contain nicotine, and thus share addictive properties with products that are already regulated under chapter IX of the FD&C Act.

(ii) *The long-term health risks associated with the usage of the various tobacco products, notably, increased risks of heart diseases, pulmonary diseases and cancers, and more generally premature death.*9

There is substantive evidence that the use of cigars and pipe tobacco is correlated with an increased likelihood of developing lung, oral cavity, larynx and esophagus cancer, increased risk

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7 79 FR 23153
8 79 FR 23155-23158
9 79 FR 23154
of coronary heart disease, and chronic obstructive pulmonary disease (COPD). Estimates of life expectancy loss linked to cigarettes smoking are available and cited in the Regulatory Impact Assessment. For instance, a study by Frank et al. (2004)\textsuperscript{10} shows that the life expectancy of a 24 year old cigarette smoker is reduced by 2.4 years compared to a non-smoker for women, and by 4.4 year for men. FDA anticipates that cigar smoking triggers many of the same diseases as cigarettes, albeit at a possibly lower rate due to less frequent consumption and a lower tendency to inhale. Conversely, the existing evidence for novel products such as e-cigarettes is still indecisive. For instance, FDA cites several studies that found the existence of certain toxicants in e-cigarette devices.\textsuperscript{11} On the other hand, the agency also cites research finding that e-cigarettes’ toxicant level is significantly less than in cigarettes and similar to levels contained in well-recognized nicotine-replacement therapeutic treatment.

There is indeed mounting evidence that e-cigarettes are effective cessation devices. A study from the UK—released after the publication of this proposed rule—found that people who attempt to quit smoking without the assistance of professionals are 60% more likely to report being successful if they resort to e-cigarettes than if they rely only on willpower or on over-the-counter replacement patches and gels. The study is based on a survey of close to 6,000 smokers between 2009 and 2014 and controls for a range of possible confounders. The lead investigator concludes that while the health risks associated with e-cigarettes remain unclear, the magnitude of these risks is definitely negligible in comparison to regular smoking.\textsuperscript{12} Meanwhile, a recent report from the French Council on Public Health (Haut Conseil de la Santé Publique) released on May 28th, 2014 unanimously corroborates the finding that the public health risks linked to e-cigarettes are considerably lower than those associated with the use of tobacco. However the council also warns about the prominent practice of co-using e-cigarettes with regular tobacco and about the fact that using e-cigarettes is likely to be gateway to future tobacco use for adolescents.\textsuperscript{13}

\(iii\) The consumer confusion and misinformation about certain covered tobacco products.\textsuperscript{14}

FDA contends that the mere fact that many tobacco products are currently not regulated by the agency confuses people into thinking that these products are safe. This risk of confusion is even more likely among adolescents, which is the prime age when most tobacco users begin to develop their behaviors. According to the agency, if this initiation during childhood or

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\textsuperscript{10} Food and Drug Administration, Preliminary Regulatory Impact Analysis – Deeming Tobacco Products to be Subject to the Food, Drug, and Cosmetic Act, Reference 68.
\textsuperscript{11} Food and Drug Administration, Preliminary Regulatory Impact Analysis – Deeming Tobacco Products to be Subject to the Food, Drug, and Cosmetic Act, References 41 & 105.
\textsuperscript{13} Haut Conseil de la Sante Publique (2014) Avis relatif aux bénéfices-risques de la cigarette électronique ou e-cigarette étendus à la population générale.
\textsuperscript{14} 79 FR 23158
\end{flushright}
adolescence is prevented, most individuals are unlikely to ever start smoking.\textsuperscript{15} FDA states: “Virtually all new users of most tobacco products are youth, and a reduction in tobacco product use by this population alone could significantly reduce tobacco-related death and disease in the US.”\textsuperscript{16} Moreover research finds that young people may not have the full capacity to make a rational decision about smoking, involving a consideration of risk and benefits, as well as long term effects. Additionally, some studies found that adolescents seem to overestimate their ability to quit smoking.

\textbf{1b. Magnitude of the Problem}

Although the scope of the problem is rather well-defined in the proposed text, there is no clear estimate of the magnitude of the public health challenge posed by currently unregulated tobacco products. The lack of information on the magnitude of the problem hinders the retrospective review (as well as the development) of the regulation, because FDA has no baseline from which to measure success. The RIA cites a 2011 national survey estimating the number of people aged 12 and older who had smoked in the past month to be 13.2 million for cigars and 2.1 million for smoked pipe tobacco.\textsuperscript{17}

According to the same survey, 37 percent of the people who reported that they first used cigars in 2010 were under the age of 18—about 1.1 million. The FDA further explains that this figure is likely to be an underestimation of the true population of young people initiating the use of cigars in 2010 because survey respondents do not systematically identify the tobacco product they use as cigars.

However, no such estimate is available for other tobacco products that would be subject to the deeming under the proposed rule (e.g., e-cigarettes, gel, hookahs). The degree of uncertainty is particularly high with regards to the magnitude of the effect of e-cigarettes: while the use of this product has increased rapidly in the past few years it is difficult to predict whether this growth will continue, level-off or decrease. Additionally, the magnitude of the challenge represented by e-cigarettes on public health depends on its health effect, which is largely unknown to date, as well as on its relation with other products. As aforementioned, it is still unclear whether e-cigarettes are a substitute for normal cigarettes, whether they help smokers quit smoking, or on the contrary whether they increase initiation to tobacco products amongst youth, or whether they are simply co-used with other tobacco products (complements).

Determining more clearly the magnitude of the problem and of its various facets would also help adjudicate between option 1 and option 2. Indeed, option 1 — deeming all products that meet the statutory definition of “tobacco products” to be covered by chapter IX of the FD&C Act—is

\textsuperscript{15} 79 FR 23153
\textsuperscript{16} 79 FR 23155
\textsuperscript{17} 79 FR 23198 Ref. 25

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premised upon the idea that all of these products potentially pose a high risk to public health. On the other hand, option 2 would exempt “premium cigars” from the coverage on the ground that these cigars do not represent a serious enough risk for the general public. The rationale behind this option is that while all products are harmful and addictive, some are more harmful and addictive than others, thereby delineating a “continuum of Nicotine-Delivering products.”

Arbitrating between the two options warrants stronger baseline information on various causal mechanisms: e.g., frequency of use, use patterns by youth and young adults, and health risk of consumption without inhalation. Determining whether cigars create dependence is indeed mediated by a range of factors as laid out by the FDA “based on the degree of cigar smoke inhalation, the rate of oral nicotine absorption, the development of tolerance to nicotine, the age of initiation, and the duration of exposure.”

2. Explaining the Intervention Logic

Another important step in ensuring that a regulation is laid out in a way that makes it amenable to retrospective review (as well as successful in achieving its goals) is that it uses a clear causal language and logic. Particular attention should be paid to consistently distinguishing between the rule, its implementation, its direct outputs, and the medium to long-term intended outcomes. Given the inherent complexity of the causal logic underlying the proposed rule, its multiple components and mediating factors, it is unlikely that the retrospective review will use an experimental design. Rather, the regulation is more amenable to an impact-oriented approach in which causality is inferred from information about the causal chain—often referred to as theory-based evaluation. This evaluation approach hinges on the principle of causal theory of change, also called intervention logic; hence the necessity for the FDA to clearly lay out at the outset the logic of its regulatory intervention.

In this section we review whether the FDA has clearly laid out how the proposed rule is intended to solve the identified problems. While the proposed rule contains many of the necessary elements of a logic framework/theory of change, it does not present these various elements in a well-articulated manner that would allow an ex-post evaluator to immediately identify:

(i) What the intended short and long-term outcomes of the regulation are.
(ii) What assumptions underlie the intervention model (which need to be verified for the intended outcomes to be achieved).

18 79 FR 23147
19 79 FR 23154
(iii) What mechanisms need to be activated for the regulation to be effective.

An evaluator would thus need to reconstruct the logic behind the regulation prior to embarking upon a meaningful retrospective review. In the following sections we show how the FDA might want to reorganize the rule to emphasize the intervention logic.

2a. General Intervention Logic

In order to address the three main problems linked to the current lack of regulation of many tobacco products, the proposed rule introduces a number of regulatory provisions that fall into three categories:

- **Statutory provisions contained in Chapter IX of the FD&C Act**

By extending coverage of all the tobacco products that match the statutory definition to provisions of the FD&C Act, this proposed rule would trigger a number of automatic clauses and requirements:

  - Prohibition of adulteration and misbranding (section 902 & 903 of the FD&C Act),
  - Requirements for ingredient listing and reporting of HPHCs (section 904 of the FD&C Act),
  - Requirement for registration and product listing (section 905 of the FD&C Act),
  - Review of premarket applications and “substantial equivalence” (SE) reports (section 905 & 910 of the FD&C Act),
  - Elimination of “light,” “low,” and “mild” descriptors and unproven modified risk claims (section 911 of the FD&C Act),
  - Prohibition of free samples (section 102 of the FD&C Act), and
  - Authority to propose product standards for proposed deemed tobacco products (section 907 of the FD&C Act).

As summarized in Figure 1, we infer from the proposed rule that these provisions are intended to contribute to the following outputs:

  - Increased information about current and future products’ components, ingredients and health risks,
  - Increased control over market access by the FDA,
  - Decreased misinformation and confusion of users and potential users, and
  - Curtailed access to the products by youth.

- **Additional access provisions**

Given that the automatic provisions only have an indirect causal relationship with the intended outcomes, the FDA proposes to add more direct control mechanisms over the availability of
information about the health risks of these products and over their accessibility by youth and young adults. Consequently three additional access provisions are proposed:

- Mandatory health and addiction warnings,
- Access restriction under age 18, and
- Prohibition on vending machines.

We gather from the text that the additional provisions are intended to contribute to the following outputs:

- Improved customer awareness on actual health risks of the products and
- Reduction in the number of access pathways to the product by youths and children.

• **Enabling nature of the rules**

Finally, this proposed action differs from typical public health regulations insofar as it is an “enabling regulation.” In addition to directly applying the substantive requirements of chapter IX of the FD&C Act, it also provides the agency with the ability to issue further public health regulations related to these products both for products deemed in the present rule and for future products emerging on the market. This general enabling condition is designed to empower FDA to exert more authority over the manufacture of these products and have some control over which products can and cannot enter the market.

From an evaluative perspective, it is important that the proposed rule logically connects these various provisions to the problems at hand and clarifies how the provisions will address the various dimensions of the identified problems. While most of the necessary information about the logic of intervention is contained in the text, it is presented in a patchwork and would benefit from a more streamlined and consistent presentation.
**Figure 1. Overall Intervention Logic of the Proposed Rule**

**Provisions**

**Chap IX FD&C Act**
- Ingredient lists
- Registration
- Product lists
- Pre-market review (SEP)
- Prohibition of modified descriptors
- Prohibition of free samples

**Added access provisions**
- Health warning
- Addiction warning
- Age restriction under 18
- Prohibition of vending machine

**Outputs**

- Improved FDA information on current & future products
- Increased power of FDA to control market access & quality control
- Improved customer awareness on health risks
- Fewer pathways for youth access to products

**Intermediary outcomes**

- Increase number of people quitting
- Decrease use
- Reduction in tobacco initiation
- Increase in compensatory health behaviors
- Decrease in substitution and co-use
- Increased quality of products allowed on the market

**Long-term public health outcomes**

- Increased longevity
- Decreased morbidity

Source: Author’s reconstruction based on elements from the proposed rule and the regulatory impact assessment
2b. The Status Quo and Elements of Counterfactual

In many evaluations, including retrospective regulatory reviews, the relative success or failure of an intervention is determined by comparing what would have happened without the rule (the counterfactual) to the changes that took place given the presence of the rule. In order for this comparison to be possible, it is important that the status quo and the interventions be well defined. The proposed rule lays out rather clearly the various alternative scenarios. Given that the rule consists of two co-proposals, option 1 and option 2, there are in fact three possible scenarios as summarized in Table 1.

Table 1. Co-proposals

<table>
<thead>
<tr>
<th>Status quo</th>
<th>Option 1</th>
<th>Option 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulated</td>
<td>Not Regulated</td>
<td>Regulated</td>
</tr>
<tr>
<td>Cigarettes</td>
<td>Accessories</td>
<td>Current tobacco products</td>
</tr>
<tr>
<td>Roll-your own tobacco</td>
<td>Other tobacco products</td>
<td>(dissolvable, gels, hookah tobacco, e-cigarettes, cigars, pipe tobacco)</td>
</tr>
<tr>
<td>Smokeless tobacco</td>
<td></td>
<td>Parts &amp; Components</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Sold separately or as part of kits e.g., air/smoke filters, tubes, papers, pouches, flavoring, cartridges for e-cigarettes Future products, parts and components</td>
</tr>
</tbody>
</table>

Source: Author based on regulatory impact assessment

Moreover the FDA attempts to lay out some cursory elements of a counterfactual, describing heuristically what would happen without the regulation:

- “Without deeming these products to be subject to the FD&C Act, FDA would lack the authority to collect vital ingredient and health information about them. We would also lack the authority to take regulatory action with respect to them, if we determined it was appropriate to do so.”21
- “Without the proposed rule, new products would be developed that pose substantially greater health risks than those already on the market, the premarket requirements made

21 79 FR 23196
effective by this proposed rule would prevent such products from appearing on the market and worsening the health effects of tobacco product use.”

However, the text remains focused on the regulatory authority of the FDA itself and says very little about the greater purpose of this enhanced regulatory authority, in particular in terms of the change in health outcomes or in terms of the enhanced prevention of addiction among youth.

FDA is rather candid about the limited availability of rigorous evidence about the actual health risks associated with the novel tobacco products currently available on the market. The agency also acknowledges that use patterns of these products (notably in terms of substitution or co-use with cigarettes) remain largely unknown. Nonetheless, despite these multiple unknowns, FDA overlooks possible offsetting effects that would possibly produce unanticipated negative effects of the regulation. For instance:

- The possibility that once other tobacco products are regulated, consumers switch back to cigarette use which may be more harmful.
- The possibility that the costs for manufacturers incurred by the new regulation could discourage the development of new products in general, including products that would be less harmful than those currently available.
- The possibility that e-cigarettes constitute an effective device to help smokers become ex-smokers.

Overall, the FDA could strengthen the proposed rule’s readiness for retrospective review, and probably improve the rule itself, by plainly laying out the assumptions underlying its intervention logic.

2c. Application of the Precautionary Principle

While FDA does not make an explicit reference to the ‘precautionary principle’ or the ‘precautionary approach’ to rule-making, it is evident from the text that this principle is the main causal mechanism underlying the proposed rule. The precautionary principle is typically used by policy-makers to justify regulations or discretionary decisions in situations where there is the possibility of harm from making a decision (or deciding not to intervene) and where extensive scientific knowledge on the matter is lacking. In this particular regulation, FDA implicitly invokes a responsibility to protect the public (particularly youth) from exposure to harm when researchers have found at least a plausible risk linked to the consumption of these novel tobacco products. Usually these preemptive protections can be relaxed if further rigorous evidence emerges that no harm actually results.

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The invocation of a form of precautionary principle is most evident for electronic cigarettes, for which there is to date very little evidence on their effects on public health. On the one hand, FDA has found presence of harmful chemicals in both the cartridge and the aerosol of some e-cigarettes. On the other hand, some studies show that while e-cigarettes have toxicants, their level is much lower than for traditional cigarettes. As aforementioned, some researchers evoke the possibility that e-cigarettes are less hazardous because they are noncombustible, thereby reducing risks from carcinogens smoke and dangers of secondhand smoke. Moreover, some researchers claim that e-cigarettes are used as a transitional device to help current cigarette smokers quit smoking altogether. The Journal of the American Medical Association’s patient page on e-cigarettes contains the following list of potential benefits:

- Tobacco is what makes regular cigarettes so harmful to health. e-Cigarettes do not contain tobacco.
- Tobacco products are addictive because of the nicotine they contain. Nicotine is not healthy. However, it probably does not contribute nearly as much to smoking-related diseases as tobacco does.
- Other types of “clean nicotine” have been used as a safe way to help people quit smoking for nearly 3 decades. Products include patches, lozenges, gum, oral inhaled products, and nasal spray.
- Although e-cigarettes may contribute nicotine vapor to the air, the vapor is much less toxic than secondhand tobacco smoke.

According to FDA, the presence of toxic chemicals at least in some e-cigarettes and the fact that they all contain nicotine is sufficient ground for warranting FDA oversight over these products, as proposed. Additional justifications include: the lack of quality control and discrepancy between actual nicotine levels and those advertised on the label. An added factor in the decision to include e-cigarettes in the list of tobacco products subject to the deeming is the existence of flavored e-cigarettes that have the potential to appeal to youth. Nevertheless, the evidence that FDA puts forth to support a trend in e-cigarette use among youth is anecdotal at best. The proposed rule cites a number of newspaper articles where students declare liking flavored e-cigarettes.

FDA should seek to evaluate the effectiveness of its precautionary approach to regulation by laying out clearly what assumptions need to be verified for the precautionary logic to yield its intended purpose. In the following section we review these assumptions and the causal

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23 79 FR 23157
24 Deborah Tolmach Sugerman, “e-cigarettes,” Journal of the American Medical Association 311, no. 2 (January 8, 2014). Available at: http://jama.jamanetwork.com/article.aspx?articleid=1812964. The patient page also lists potential concerns, noting that “Much of the concern about e-cigarettes comes from a lack of information about the product. There is also a lack of standardization and quality control among the more than 250 brands.”
25 79 FR 23157
connection that the FDA makes between the proposed provisions and the overarching goal of the regulations.

2d. Assumptions and Linkages

Through the proposed provisions, FDA intends to modify the behavior of current or potential tobacco users ultimately to enhance their health outcomes (increased longevity and reduced morbidity). In order for these outcomes to materialize, a number of causal mechanisms need to be activated. It is the FDA’s task to make these assumptions very clear so reviewers can both consider the merits of the proposal, and, if the rule is finalized, retrospectively verify whether these mechanisms have indeed been activated, thereby ensuring that the regulations has made a significant contribution to public health. Some of these mechanisms are laid out in the text:

- Likelihood that existing users of tobacco products will stop using such products
- Likelihood that those who do not use these products will start using them
- Likelihood that users of these product could co-use or migrate to other (more harmful) tobacco products like cigarettes
- Awareness about various tobacco products’ harmfulness and addictiveness of cigars, hookahs, e-cigarettes

Table 2 provides a brief summary of outcomes of interest and the provisions that may contribute to them.

Table 2. Expected mid-term outcomes and their underlying provisions:

<table>
<thead>
<tr>
<th>Increased information for FDA</th>
<th>Improved information for consumers</th>
<th>Control of market entry (and innovation)</th>
<th>Protection of Youth</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ingredient list</td>
<td>Health warning (access provision)</td>
<td>Pre-market review of current products</td>
<td>Prohibition of distribution in vending machine (access provision)</td>
</tr>
<tr>
<td>Registration and product listing</td>
<td>Prohibition of modified descriptors</td>
<td>Capacity to control entry of future products</td>
<td>Prohibition of free samples</td>
</tr>
<tr>
<td>“FDA regulated”</td>
<td></td>
<td></td>
<td>Requirement of a minimum age for purchase (access provision)</td>
</tr>
</tbody>
</table>

Source: Author based on proposed rule

What follows is a detailed description of one of the access provisions—the minimum age requirements—and how the FDA assumes it will contribute to the intended change in public health:
• “The goal of the proposed age restrictions is to reduce youth initiation of tobacco use, thereby reducing the number of people who suffer from tobacco-related illnesses and heath and the number of people who are exposed to secondhand smoke.”  

• “More uniform enforcement by FDA working in conjunction with states would minimize youth’s ability to circumvent the current patchwork of youth access restrictions by attempting to buy tobacco products in jurisdictions where enforcement may be more lax.”

• “FDA concludes that the proposed minimum age and identification restrictions, combined with comprehensive and consistent enforcement at the Federal level and in partnership with states, will decrease the likelihood of youth smoking initiation.”

However, as graphically shown in Figure 2, the success of this provision hinges on the realization of a number of necessary conditions: the effective enforcement of the rule by the retailers, the wide exposure of the public to the purpose of the age restriction, the absence of readily available substitutive source of provision.

As described above, the proposed rule contains an array of provisions that are supposed to contribute to the overarching goal motivating the regulation, i.e., enhancing public health. As with any intervention or policy, the regulation is rife with assumptions of how it ‘would work’ to bring about the intended change. Given that this regulation is focused on changing behaviors and preventing addictive behaviors it is inherently complex with a range of necessary conditions. In the retrospective review the evaluator will need to assess whether these causal packages worked and brought about the intended change. The proposed rule should ensure that its underlying theory of change is clearly defined and transparently exposed.

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26 79 FR 23160
27 79 FR 23161
28 79 FR 23161
Figure 2. Reconstruction of the age restrictions provision logic

Source: Author’s reconstruction based on proposed rule
3. Measurement Criteria

In order to measure whether this regulation is successful following its implementation, it is necessary for the FDA to define what success looks like. Defining metrics of success is thus an important element of any proposed rule. Any such metrics should be directly linked to the identified problem, and measure the change in the outcomes of interest that can be attributed to the implementation of the various provisions contained in the proposed rule.

Regrettably, FDA does not explicitly mention the use of any metrics to evaluate its proposed rule, nor does it lay out a plan to devise such metrics. Moreover the agency admits that it lacks sufficient data for quantifying the intended benefits of the proposed rule. Benefits are especially difficult to quantify because they are not fully internalized by consumers who stop consuming tobacco. There are issues of second-hand smoking (negative externalities) as well as issues with self-control, addiction and time-inconsistent behavior.

Given the complexity of the problems that the regulations is intended to tackle, the non-linearity of the causal pathways that tie the provisions together, as well as the range of unknown factors that will mediate the effectiveness of the regulation implementation, FDA should better distinguish between three levels of results: outputs (more direct, short term, and readily measurable), medium-term, and long-term outcomes (the results of these activities or services). Such differentiation is not done in the proposed rule and could be amended along the following lines.

3a. Output Metrics

Outputs are the direct and measurable products of a program’s activities or services. Outputs are typically expressed in terms of units. In the text a number of direct, tangible, and short term results are presented:

- Improved knowledge base of the FDA on the various tobacco products.
- Provision of information about number and location of regulated entities to establish effective compliance programs.
- Reduce misleading claims and enable better decision making by consumers.
- Barriers to market entry for more harmful products (enabling regulation)

Based on these outputs a number of metrics could be devised:


• Number of ingredient listings collected by the FDA
• Number of reports of hazardous constituents captured by the FDA
• (Reduction in) number of vending machines with tobacco products
• (Reduction in) number of misleading claims and improper information
• Number of tobacco products with health warnings on their packaging
• Number of retailers complying with age restrictions

3b. Outcome Metrics

While the FDA does not explicitly propose any outcome metrics, it nonetheless lists a number of intended outcomes (benefits) of its proposal that could be measured and quantified with more available data.

• Reduced use of tobacco products
• Engagement in compensatory health behaviors
• Prevention of more harmful products from appearing on the market (prevents worse health effects)
• Enhanced power of the FDA over future tobacco products
• Improved health and longevity
• More efficient enforcement of regulations for all tobacco products linked with harmonization across the US territory
• Modified social norms
• Reduced substitution effects

Based on this non-differentiated list of benefits, the FDA should distinguish between two types of outcome metrics as suggested below.

Medium-term Outcome Metrics

While outputs are products or services directly unfolding from the regulatory activities, outcomes are the results of these activities and can take longer to come to fruition. They can also be more loosely connected to the direct rule due to mediating factors that enable or disable positive impact. Outcomes are often expressed in terms of an increase in understanding, and improvements in desired behaviors or attitudes of participants.

Given that the regulation is intended to change people’s behavior, most substantive effects of the regulations will only come about in the long-term. Moreover, given the complexity of the sought after behavioral change, the impact trajectory of the regulation is likely to be non-linear. Measuring long term impacts and attributing realized progress to the regulation will therefore be a daunting task. However, it is possible to identify a number of outcomes which are likely to be realized in the near to medium term. The bulk of the measurement effort should thus be focused
on these measurable and tangible results. Since FDA does not identify these metrics, we propose a number of possible options:

- Reduction in the number of young people initiating the use of tobacco products
- Increase in the number of people who quit using tobacco products
- Reduction in the number of people who use tobacco products
- Number of new tobacco products that are more hazardous entering the market within 5 years
- Number of innovative tobacco substitutes that are less hazardous entering the market within 5 years

**Long-term Outcome Metrics**

As described in the RIA, “FDA anticipates that the largest benefit of the proposed provisions would be the improvements in health and life expectancy resulting from reductions in the use of combustible tobacco products deemed under the rule.” Nevertheless, the impact categories are not specifically defined in the regulation and no clear indicators are cited. Below we propose a sample of metrics that should be monitored:

- Reduction in consumption of tobacco products by youth under 18 years old
- Change in rate of cancer attributable to consumption of tobacco products or second-hand smoke
- Change in rate of heart-disease attributable to consumption of tobacco products
- Change in rate of pulmonary disease attributable to consumption of tobacco products

**3c. Cost Metrics**

The remaining metrics pertaining to cost and to implementation of the regulation are important to measure insofar as they inform FDA on the reliability and validity of its ex ante impact assessment and can be used to improve future analysis.

- Registration costs
- Submission costs
- Labeling costs
- Removing non-compliant point of sale ads
- Cost of complying with vending machine restrictions
- Reduced revenues for firms in sector
- Fall in tax revenues (excise taxes)

In Table 3 we present the costs and benefits of the proposed rule as estimated by the agency.

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4. Information collection

First, it is necessary to make a distinction between two types of evidence that will be necessary to collect for the retrospective review of this proposed rule. On the one hand, the FDA should gather epidemiological evidence of the various tobacco products’ health effects. On the other hand, FDA should also collect information on the implementation of the rule and monitor data on the various metrics described above. While the regulation should be in tune with the latest epidemiological research, the object of this comment is circumscribed to assessing the evaluability of the rule. Thus, the causal evidence that we focus on is restricted to the evidence necessary to validate the theory of change of the regulation.

4a. Baseline

As aforementioned, the baseline information for the rule is rather weak at multiple levels:

- Regarding the magnitude of the issue
- Regarding the use patterns (by whom, co-use, etc.)
- Regarding the effects of different products on health and addiction

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The weakness of the baseline information is most glaring with regard to e-cigarettes. FDA concedes “we do not currently have sufficient data about e-cigarettes and similar products to determine what effects they have on the public health” and adds “without more data, it is not possible to know the impact of these products either on reducing usage of cigarettes or in possibly prolonging usage of cigarettes while continuing to expose users to the harmful carcinogens in combustible tobacco products.”

FDA’s baseline for the use of e-cigarettes relies on a number of surveys, some of which are nationally representative. For instance, FDA reports the results of the National Youth Tobacco Survey administered to middle and high school students and shows that the use of e-cigarettes among this population has more than doubled between 2011 and 2012. However, given the recentness of the e-cigarettes phenomenon, no longitudinal study is available to corroborate the findings of studies which offer a snapshot of use at a given point in time.

The lack of a solid baseline will undoubtedly constitute a major challenge for the retrospective regulatory review aimed at assessing the change after the implementation of the regulation.

4b. Evidence Base for the Effectiveness of the Various Regulatory Mechanisms

The effectiveness of the proposed rule in averting public health risks linked to tobacco products will depend on a range of factors, most notably key mediating parameters: (i) the health effects of the different products; (ii) the use patterns; (iii) the efficacy of the various provisions to modify behavior as intended by the text. Regarding this latter parameter, the FDA relies on the evidence of the effectiveness of past similar regulations; most notably the track record of the agency with the implementation of Chapter IX of the FD&C Act with the four tobacco products already covered (i.e., cigarettes, roll-your own tobacco, etc.). While the evidence base regarding the effectiveness of the enforced minimum age requirements is undeniably strong, other provisions of the proposed rule are not supported by an equally solid track record of success.

Age Restriction Clause

The discussion of the effectiveness of the proposed restrictions and the standard under Section 906 (d) are enlightening regarding the challenges of attributing the positive outcomes to a given set of regulatory provisions. The complexity of the attribution task further warrants the systematic collection of information both during and after implementation of the rules to assess whether the output and outcome metrics are met and the goals accomplished.

Based on past experience, FDA asserts that the prohibition of sales under the age of 18 would be particularly effective in reaching “the goal of reducing youth initiation of tobacco use and cutting

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32 79 FR 23152
33 79 FR 23198 References 4 & 37
the number of people who suffer from tobacco-related illnesses.” Indeed, FDA relies on sufficient evidence that enforced minimum age requirements and identification requests are effective in reducing illegal sales of tobacco to youth. However, there are conflicting findings about whether this reduction in sales ultimately contributes significantly to reducing the rate of tobacco product use among adolescents. These mixed-findings on the impact of youth access laws on youth tobacco use can be explained by a range of factors, notably the uneven enforcement of age restrictions across states, and the youth resorting to social sources of tobacco (friends, parents, etc.). FDA posits that by applying a federally mandated age requirement, this proposed rule would circumvent youth’s ability to navigate the “patchwork of youth access restrictions to buy tobacco products in jurisdictions where enforcement may be more lax” and would therefore be more effective at curbing youth usage of tobacco products. To validate this assumption in the retrospective review, FDA should commit to systematically tracking the output and outcome metrics described above.

**The ‘FDA-regulated’ Effect**

One of the main premises of this proposed regulation is that the mere fact that some tobacco products are not FDA-regulated sends confusing signals to consumers. The latter are thought to believe that tobacco products which are not subject to FDA regulation are *de facto* safe and present fewer health risks than regulated products. The agency posits that the proven substitution away from cigarettes and towards other tobacco products is not simply due to a difference in pricing but also to a difference in the regulatory regime of these two categories of products. Their conjecture is that covering the other tobacco products will produce results tantamount to those achieved with conventional tobacco products, such as cigarettes and roll-your-own tobacco. However, for the transferability of these findings to be warranted, the following assumptions need to be validated: (i) the audience is the same and reacts in a similar manner to the health and addiction warnings and the access restrictions; (ii) the use patterns are similar; (iii) the substitution effects are similar. While the two groups of products have their addictive property in common, they differ on a number of other characteristics, including the risks they pose to smokers and third parties. Once again, systematic collection on the various effectiveness metrics is necessary.

**4c. Possible Sources of Information**

**Requests for Comments**

Although FDA does not explicitly lay out a plan for collecting the missing baseline data, the proposed rule contains a commitment to bridge some of the information gaps identified in the

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34 79 FR 23160  
35 79 FR 23161  
36 79 FR 23161
preamble. FDA notably aims to “continue to research how e-cigarettes use is impacting the public health” and invites public comment, including supporting facts, data, research, and other evidence on the various dimensions for which the knowledge base is still mixed. For example the agency requests factual comments on:

- Relative hazard of non-combustible vs. combustible tobacco products,
- E-cigarettes as cessation devices for cigarette smokers,
- Impact of novel tobacco products on non-users,
- Rate of substitutions between cigarettes and other tobacco products due to the taxation and regulation of the former and not the latter,
- Net public health impact at the population level (which requires an assessment of the impact on initiation, cessation and product harm),
- Differentiated hazard level by various tobacco products, and
- Cigar smoking addictive properties.

**Other Sources of Information**

FDA also rightfully relies on the information that will come automatically from the application of the regulation. Through the various provisions under chapter IX, the FDA should be able to gather information on the various products’ key characteristics such as:

- Product registration (labeling, sample of product),
- List of ingredients (including tobacco substance, compounds & additives),
- Tobacco health documents submitted by the manufacturers with information relating to health, toxicological, behavioral or physiological effects of current or future tobacco products, their constituent, ingredients, components and additives, and
- Information derived from pre-market reviews.

The Regulatory Impact Assessment also discusses other sources of information, notably:

- CDC report on pattern of cigarettes and cigarette equivalents consumptions,
- GAO reports on sales of various tobacco products, and
- Various national youth surveys.

Finally, the agency expresses its commitment to keep abreast of scientific developments regarding the efficacy of the final health warnings and ways in which their efficacy could be

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37 79 FR 23152

38 Food and Drug Administration, *Preliminary Regulatory Impact Analysis – Deeming Tobacco Products to be Subject to the Food, Drug, and Cosmetic Act*, page 11
improved. “We will use the results of our monitoring and such research to help determine whether any of the warning statements should be revised in a future rule making.”

Although requesting factual comments and using existing research can certainly be considered a step toward the appropriate level of information collection, there is no guarantee that FDA will get all the needed data. The request for comments cannot be regarded as a sufficient information collection and cannot make up for an explicit commitment from the agency to collect and analyze information on a set of clearly specified metrics. Consistent with the requirements of the Paperwork Reduction Act, FDA should commit to collecting the information needed to evaluate the rule’s success.

5. Timeframe

The text of the proposed rule does not include a timeframe for retrospective review. In the final rule, FDA should commit to measuring some of the above stated metrics and verify the assumptions underlying the model on a regular basis to provide timely feedback on the rule’s outputs, outcomes, costs and unanticipated consequences.

Given that currently the baseline is rather weak, the FDA could start collecting data prior to the full enactment of the rule—planned for 30 days after date of publication—which could allow the retrospective review to adopt an evaluation design utilizing the variation in the timing of implementation (e.g., interrupted time series). Additionally, the monitoring of certain metrics needs to take place during the full implementation period. On the other hand, some behavioral changes are expected to be immediate and others are likely to be more long-term, so the evaluation period needs to span several years.

Recommendations

Contrary to other types of intervention geared at improving health outcomes of people or empowering smokers to quit smoking, a regulation relies on indirect causal mechanisms to reach its overarching goal. From an evaluative standpoint, this makes a regulation a complex intervention, as processes of change are often non-linear; they rely on behavior change through causal mechanisms such as: deterrence, prohibition, information, etc. In the particular context of this FDA regulation another set of complex factors comes into play as there is limited data on the actual health impact of the novel tobacco products on health outcomes and addiction patterns. Naturally, there are many unknowns in the proposal, in particular, a lack of evidence specifically about differentiated public health impacts of various tobacco products and of baseline usage patterns and risks. We thus invite the agency to take the following principles into account in the final version of the proposed rule:

39 79 FR 23165
1. Choosing between Option 1 & 2

The two co-proposals presented in the proposed rule are motivated by two different logics. On the one hand, option 1 applies a precautionary approach to rule-making and deems potentially dangerous all products that contain nicotine, expressing a responsibility to protect the larger public in the absence of full scientific certainty about the risks incurred by novel tobacco products. On the other hand, by exempting ‘premium cigars’ from coverage and additional access provisions, option 2 relies on the logic of a ‘continuum of nicotine delivery.’ Under this latter option, some products are considered more dangerous than others and therefore exempt from regulation. The FDA decision of exempting premium cigars from the regulatory framework of the FD&C’s chapter IX does not seem fully evidence-based given that recent research seems to indicate that e-cigarettes are also relatively more innocuous than other tobacco products. Before adjudicating between the two options, FDA should lay out clearly the overarching goals sought out by the regulation as well as the assumptions underlying the intervention logic. The agency should also seek to strengthen its baseline data, notably with regards to the magnitude of the public health challenge posed by the various novel tobacco products.

2. Preparing for the Retrospective Review

FDA should add language to its final rule committing to measure efficacy at two-year increments following implementation of the rule, measured notably as percent reductions in use of the various tobacco products subject to coverage. This information will tell both the agency and the public how valid its theory of change was, and will provide information for future rulemakings on how to tailor regulatory provisions to achieve desired outcomes. In addition, retrospective review efforts may be able to provide information on whether the exemption of some products (potentially premium cigars and e-cigarettes) was appropriate for maximizing net benefits. If the retrospective reviews indicate that FDA’s regulatory provisions were ineffective, FDA should consider a rulemaking to change the rules or accompany them with supporting training or public awareness campaigns to best reflect the lessons learned.

3. Dealing with Uncertainty

While the agency rightfully acknowledges the relatively weak evidence about the health risks linked to many of the currently unregulated products, it only timidly shows a commitment to bridging this knowledge gap. In order to better address the uncertainty surrounding this rule-making, the agency should:

- Transparently expose the theory of change underlying the various provisions as well as the causal mechanisms which need to be activated for the rule to be successful,
- Clearly delineate the various scenarios and their expected impact, and
- Commit to systematically collecting information on the implementation of the various provisions, their outputs and medium-term outcomes.
Moreover, in regulations attempting to trigger behavior change amongst addicted people, causal processes are bound to be complex, with non-linear and non-proportional effects. Consequently, the agency should commit to assessing potential unintended consequences of its rule making as an inherent part of the retrospective review’s scope.