Regulation Review

Final FDA E-Cigarettes Rule

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The Food and Drug Administration (FDA) recently released the final version of its rule regarding tobacco products. The rulemaking would expand the scope of the FDA's regulatory authority over tobacco products to include, among others, smokeless devices such as e-cigarettes. Under this regulatory framework, many newer products could face greater barriers to entering or even staying in the market. The American Action Forum (AAF) previously reviewed the proposed version here. The unofficial, pre-publication version is 499 pages.

BREAKDOWN

Proposed Rule:

- Total Costs: $1 billion
- Annual Paperwork: 634,250 hours

Final Rule:

- Total Costs: $1.1 billion
- Annual Paperwork: 1,633,554 hours

ANALYSIS

Total costs remain largely the same from the proposed version, yet the paperwork burden increases by roughly one million hours. How does this happen? First, on the cost estimate, FDA has decided to finalize "Option 1" from their proposal. The other option that the FDA considered (Option 2) would provide an exemption for "premium cigars." However, the agency agreed with commenters "that deeming all cigars, rather than a subset, more completely protects the public health," despite lower compliance costs. As in the proposed version, the FDA was unable to quantify the rule's benefits, but instead noted:

> Among other effects, new products will be subject to an evaluation to ensure they meet the appropriate public health standard for the pathway before they can be marketed, labeling cannot contain misleading statements, and the FDA will be made aware of the ingredients in newly deemed tobacco products.

The main part of the paperwork spike is a nearly ten-fold increase in the "Applications for Premarket Review of New Tobacco Products," from 135,432 hours in the proposed version to more than 1.2 million hours in the final version. Interestingly, as the FDA states: "We attribute this increase to the rapid growing ENDS [electronic nicotine delivery systems] market since the NPRM was published." More specifically, the affected entities increased from 25 in 2014 to 200 today – a dramatic increase in a matter of only two years.

The rapidly growing ENDS market (i.e. e-cigarettes, etc.) is essentially the crux of the issue surrounding this

rule. Under the authorizing statute, "deemed" tobacco products – or "substantially equivalent" (SE) products – must have been on the market as of February 15, 2007 or else they have to face full "pre-market authorization" (PMTA). (See the aforementioned 1.2 million-hour paperwork requirement.) According to FDA, "[the] burden of demonstrating that a valid predicate exists rests with the manufacturer." For a new, dynamic industry such as this, it may be difficult for individual manufacturers to easily determine if their products meet the grandfathering criteria. However, the FDA does provide a staggered compliance schedule in the final rule:

> According to this revised compliance policy, for newly deemed products that are on the market on the effective date of this final rule and were not on the market on February 15, 2007, FDA is providing a 12-month initial compliance period for manufacturers to submit (and FDA to receive) an SE exemption request, an 18-month initial compliance period for manufacturers to submit (and FDA to receive) SE applications, and a 24-month initial compliance period for manufacturers to submit (and FDA to receive) a PMTA.

Despite this accommodation, many ENDS producers – particularly smaller firms – may still face a steep compliance challenge. According to the FDA's own cost-benefit analysis, the per-entity compliance costs for ENDS manufacturers stand at "$827,000 to $1.21 million in the first year, $832,000 to $1.21 million in the second year, and $22,000 to $64,000 in subsequent years." For perspective, per Census data, the annual per-establishment payrolls for small "Tobacco Manufacturers" (NAICS 3122) are as follows:

Establishment Size	Total Payroll	# of Establishments	Average Payroll
1-4 Employees	$8,098,000	64	$126,531
5-9 Employees	$3,588,000	12	$299,000
10-19 Employees	$4,024,000	7	$574,857
20-49 Employees	$19,999,000	17	$1,176,412

The compliance costs per entity exceeds the average payroll for all four establishment classes. Granted, there may be multiple establishments under the auspices of one firm, but even then the scale of newly imposed compliance costs, versus such necessary expenses as paying employees, is substantial. It is easy to see how, according to previous estimates, 99 percent of the ENDS market is in danger under this rule. Beyond firm-level impacts, consumers could also see such unquantified costs as, "loss of product variety or higher prices."

As noted above in FDA's own analysis, this subset of tobacco products has undergone an enormous level of growth in only the past couple of years. Yet, under this regulatory framework, it has to answer to criteria from almost a decade ago. Furthermore, being "deemed" as falling under FDA's purview subjects these products to further regulatory actions – including those that could present even greater barriers to producers and consumers.