Regulation Review

Proposed Tobacco Product Regulations

MAY 5, 2014

The Food and Drug Administration (FDA) recently released its proposed rule regulating certain kinds of tobacco products. Currently, under the Food, Drug, and Cosmetics Act (FD&C Act), FDA has regulatory jurisdiction over cigarettes. This proposal would expand the breadth of FDA's regu

latory scope to include, among other items, increasingly popular electronic cigarettes (or e-cigarettes). The unofficial, pre-publication version of the proposed rule is 241 pages.

The rulemaking offers two options for consideration. Option 1 is more expansive and would cover "certain dissolvables, gels, hookah tobacco, electronic cigarettes, cigars, and pipe tobacco." Option 2 would exempt certain "premium cigars." Both options would expand the FD&C Act to implement additional measures seeking to combat underage use of covered tobacco products. Such measures would include: a standardized minimum age, expanded health warnings on products and advertisements, and a restriction on tobacco product vending machines unless the operator can protect against underage usage.

BREAKDOWN

- Option 1 Total Costs: $1 billion ($65.9 million annualized)
- Option 2 Total Costs: $779 million ($50.8 million annualized)
- No Quantified Benefits
- Total Paperwork Burden: 634,250 hours

ANALYSIS

This rulemaking was initiated in 2010, according to administration records. The result is a proposal with potential costs exceeding $1 billion and extensive new paperwork requirements. Furthermore, according to FDA's analysis, this proposal would trigger both the Regulatory Flexibility Act (RFA) and the Unfunded Mandates Reform Act (UMRA). Thus, it would impose both "a significant economic impact on a substantial number of small entities" and an annual mandated private sector expenditure in excess of $141 million. And while they discount the relative amount, FDA does admit that "some of the costs will be passed on to consumers in the form of higher prices."

FDA estimates that its proposed second option could present a substantial cost reduction, relative to the agency's first choice. Option 2 would provide a carve-out to:

> *cigars that are wrapped in whole tobacco leaf; contain a 100 percent leaf tobacco binder; contain primarily long filler tobacco; are made by manually combining the wrapper, filler, and binder; have no filter, tip, or non-tobacco mouthpiece and are capped by hand; do not have a characterizing flavor other*

than tobacco; weigh more than 6 pounds per 1000 units; and sell for $10 or more per cigar.

The agency's rationale for this exemption is that, due to the relative value and typical consumer preferences of such products, it is unlikely that there is significant appeal to potential underage users.

The proposal frames itself as primarily targeting underage usage. However, beyond the specific underage usage restrictions included in both estimates (e.g. vending machine requirements), a substantial part of this proposal is largely just establishing a framework for future regulations. As the agency notes, this is simply an "enabling regulation," or one that grants FDA the authority to enact broader measures in the future.

Although FDA has a section that discusses the quantitative health implications of e-cigarettes, they begin that section with the following: "We do not currently have sufficient data about e-cigarettes to determine what effects they have on the public health." The purported reason they are implementing this enabling regulation is to bridge that information gap. However, hundreds of millions of dollars in costs (at a minimum) are a steep price to examine a set of products that FDA concedes could be relatively less harmful than other tobacco products.

This regulation is particularly curious when, in the same rulemaking, the agency seems capable of weighing a similar level of data on premium cigars and uses that determination in the basic structure of their proposal. Perhaps as the input stage develops, FDA will be able to gather enough data through the voluntary comment process – rather than mandatory reporting procedures – to make a sound determination. Interested parties have until July 9th to submit comments.