

**The Regulatory Impact Analysis Fails to Adequately Document the Sources for the Benefit and Cost Estimates upon Which it is Based**

Docket No. FDA-2014-N-0189

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July 11, 2014

Regulatory impact analyses are required for any mandate that will result in expenditures by state, local, tribal, or private entities totaling \$141 million or more. The required analyses are described in guidelines promulgated by the Office of Information and Regulatory Affairs within the Office of Management and Budget (OIRA, 2011). The Regulatory Impact Analysis (RIA) of the proposed deeming rule contains very detailed tables claiming a wide range of costs for implementing the Proposed Rule. These costs include changes in point-of-sale advertising, labeling changes, premarket product applications, registration, ingredient listing requirements, the provision of documentation for new products, and other compliance costs. The cost estimates for annual registration are “based on FDA experience with currently regulated tobacco products” (RIA, page 29). The estimate for product listing states that “lacking estimates of the number of pipe tobacco products and electronic cigarettes produced domestically, we assume that 33 percent of pipe tobacco products are manufactured domestically...”, and again cost estimates are “based on FDA experience with currently regulated tobacco products” (RIA, page 29). Similar assumptions are made for other cost components and many assumptions are made. **No justification is presented for whether the proposed deemed tobacco products would be similar in terms of implementation costs.**

The RIA also incorporates a “welfare gain ratio” of 30 percent, thereby reducing any dollar gain in benefits to \$0.30. This number is derived from an article by Gruber and Köszegi (2001) which estimates that the welfare gain from reduced smoking would equal 16-33 percent of the monetary health gains. In their previously presented economic analysis, which was applied to the Graphic Warning Label proposal, the FDA used a welfare gain ratio of 50 percent and described as a reduction due to lost consumer surplus when smokers give up the pleasure of smoking. **However, there is no detailed empirical substantiation for the selection of the**

**current 70 percent reduction in benefits (based on only a 30 percent gain) or the change from the previously applied 50 percent.**

OIRA (2011) indicates that the agency conducting a RIA “should use the best reasonably obtainable scientific, technical, economic, and other information to quantify the likely benefits and costs of each regulatory alternative.” This standard is not met. **The FDA's failure to provide careful substantiation for the sources for the numbers presented in the RIA makes it nearly impossible to judge the veracity of the estimates, thereby precluding meaningful public comment on these important issues.**

Reference:

Gruber J, Köszegi B (2001). Is Addiction ‘Rational’? Theory and Evidence. *Quarterly Journal of Economics*, 116(4): 1261-1303, November 2001.

Office of Information and Regulatory Affairs (OIRA), Office of Management and Budget. *Circular A4. Regulatory Impact Analysis: A Primer*. August 15, 2011. Available at: [http://www.whitehouse.gov/omb/inforeg\\_regpol\\_agency\\_review](http://www.whitehouse.gov/omb/inforeg_regpol_agency_review). Accessed July 11, 2014.