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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
Docket No. Docket No. FDA–2014–N–0189

RE: 2014 Surgeon General Report and Deeming Rule

In reviewing the proposed rule I could not find a single citation to the 2014 Surgeon General's Report, *The Health Consequences of Smoking: 50 Years of Progress* (available at http://www.surgeongeneral.gov/library/reports/50-years-of-progress/index.html). This report contains important information that is directly relevant to the proposed deeming rule, including:

- The 2014 SGR contains an up-to-date estimate of the costs of smoking which shows that the costs are much higher than the 10 year old book by Sloan (which is based on even older data) that the FDA relies on in its Regulatory Impact Analysis. FDA should be using these estimates and the underlying approach, not outdated materials in its RIA.
- The 2014 SGR shows that changes to cigarettes that were thought to reduce harm actually increased harm. The FDA should take careful note of this and similar data and abandon its "continuum of risk" approach until such time that there is actual empirical evidence that products *as actually used in the population* reduce health risks.
- The 2014 SGR shows that the health risks of nicotine are more serious than previously thought; the FDA should give this information particular emphasis, especially when considering the effects of the deeming rule on vulnerable populations, such as young people and developing fetuses.
- The 2014 SGR concludes that "advertising and promotional activities by tobacco companies cause the onset and continuation of smoking and adolescents among adolescents are young adults." Absent compelling evidence that similar advertising of the tobacco products included in the deeming rule does not have similar effects, the FDA should prohibit such advertising of new products as part of this rule, and not wait the years that it will take to develop, issue, and defend a follow-up rule.

This is not the only relevant information in the Report.

The FDA needs to thoroughly review the entire report and integrate all the relevant information and, as appropriate, the supporting citations into its final rule. Failing to act on the important information in this report now will condemn hundreds of thousands, if not millions, of youth and young adults to nicotine addiction while the FDA deliberates any follow-on rules.

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