



441 G St. N.W.  
Washington, DC 20548

B-332076

April 21, 2020

The Honorable Lamar Alexander  
Chairman  
The Honorable Patty Murray  
Ranking Member  
Committee on Health, Education, Labor, and Pensions  
United States Senate

The Honorable Frank Pallone, Jr.  
Chairman  
The Honorable Greg Walden  
Ranking Member  
Committee on Energy and Commerce  
House of Representatives

Subject: *Department of Health and Human Services, Food and Drug Administration: Tobacco Products; Required Warnings for Cigarette Packages and Advertisements*

Pursuant to section 801(a)(2)(A) of title 5, United States Code, this is our report on a major rule promulgated by the Department of Health and Human Services, Food and Drug Administration (FDA) entitled “Tobacco Products; Required Warnings for Cigarette Packages and Advertisements” (RIN: 0910-AI39). We received the rule on April 6, 2020. The Congressional Record does not yet indicate the date of receipt by the House of Representatives and the Senate. It was published in the *Federal Register* as a final rule on March 18, 2020. 85 Fed. Reg. 15638. The effective date of the rule is June 18, 2021.

According to FDA, the final rule establishes new cigarette health warnings for cigarette packages and advertisements, implementing a statutory requirement that FDA issue regulations requiring color graphics of realistic images depicting the negative health consequences of smoking to accompany new warning labels. Pub. L. No. 111-31, §§ 201-202, 123 Stat. 1842-1845 (June 22, 2009). The warning labels must occupy the top 50 percent of the area of the front and rear panels of cigarette packages and at least 20 percent of the area at the top of cigarette advertisements. According to FDA, the final rule also establishes marketing requirements that include the random and equal display and distribution of the required warnings on packages, along with the quarterly rotation of the required warnings for advertisements. FDA stated it developed the rules using a science-based, iterative research process, and the agency asserts the warnings will promote understanding of the negative health consequences of cigarette smoking.

Enclosed is our assessment of FDA’s compliance with the procedural steps required by section 801(a)(1)(B)(i) through (iv) of title 5 with respect to the rule. If you have any questions about

this report or wish to contact GAO officials responsible for the evaluation work relating to the subject matter of the rule, please contact Shari Brewster, Assistant General Counsel, at (202) 512-6398.

A handwritten signature in black ink that reads "Shirley A. Jones". The signature is written in a cursive style with a large initial 'S' and 'J'.

Shirley A. Jones  
Managing Associate General Counsel

Enclosure

cc: Kenneth Cohen  
Director, Regulations Policy and Management Staff  
Department of Health and Human Services

REPORT UNDER 5 U.S.C. § 801(a)(2)(A) ON A MAJOR RULE  
ISSUED BY THE  
DEPARTMENT OF HEALTH AND HUMAN SERVICES,  
FOOD AND DRUG ADMINISTRATION  
ENTITLED  
“TOBACCO PRODUCTS; REQUIRED WARNINGS FOR  
CIGARETTE PACKAGES AND ADVERTISEMENTS”  
(RIN: 0910-A139)

(i) Cost-benefit analysis

The Food and Drug Administration (FDA) analyzed the costs and benefits of this final rule. FDA identified the costs of the rule including initial and recurring labeling costs associated with changing cigarette labels to accommodate the new cigarette health warnings; design and operation costs associated with the random and equal display and distribution of the required warnings for cigarette packages; quarterly rotations of the required warnings for cigarette advertisements; advertising-related costs; and costs associated with government administration and enforcement of the rule. FDA stated it used a 20-year time horizon and estimated that the present value of the costs of the final rule ranges from \$1.5 billion to \$1.7 billion, with a mean estimate of \$1.6 billion, using a 3 percent discount rate, and ranges from \$1.1 billion to \$1.3 billion, with a mean estimate of \$1.2 billion, using a 7 percent discount rate. FDA stated that annualized costs would range from \$100 million per year to \$114 million per year, with a mean estimate of \$107 million per year, using a 3 percent discount rate, and range from \$107 million per year to \$122 million per year, with a mean estimate of \$114 million per year, using a 7 percent discount rate. In conducting its cost benefit analysis, FDA stated it used a “break-even” approach because it concluded that the benefits here could not be quantified and so it was not possible to compare benefits and costs directly. FDA concluded that if a cost of approximately \$0.01 were assigned to the information provided by the cigarette health warning on every package of cigarettes for every package sold annually nationwide, the benefits that would be generated by the final rule would equal or exceed the estimated annual costs.

(ii) Agency actions relevant to the Regulatory Flexibility Act (RFA), 5 U.S.C. §§ 603-605, 607, and 609

FDA determined that this final rule will have significant impact on a substantial number of small entities. FDA estimated that initial costs for small manufacturers or importers affected by this final rule could represent between 2.3 and 42 percent of annual receipts, and recurring costs could represent from 0.1 to 2.7 percent of annual receipts.

(iii) Agency actions relevant to sections 202-205 of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. §§ 1532-1535

FDA determined that this final rule contains a federal mandate that will result in an expenditure that meets or exceeds expenditures of \$100 million or more, for state, local, and tribal governments, in the aggregate, or the private sector in any one year. FDA concluded that the current threshold after adjustment for inflation is \$154 million by using the most current (2018) Implicit Price Deflator for the Gross Domestic Product, and stated that this final rule will result in an expenditure in any year that meets or exceeds that value.

(iv) Other relevant information or requirements under acts and executive orders

Administrative Procedure Act, 5 U.S.C. §§ 551 *et seq.*

On August 16, 2019, FDA published a proposed rule. 84 Fed. Reg. 42,754. FDA received about 300 comments from cigarette manufacturers, retailers and retailer organizations, health professionals and researchers, advocacy groups, academic, state and local public health agencies, medical organizations and individual consumers, among others. FDA responded to comments in this final rule, grouping similar comments together according to the topic or portion of the proposed rule referenced.

Paperwork Reduction Act (PRA), 44 U.S.C. §§ 3501-3520

FDA determined that this final rule contains information collection requirements under the Act. These information collection requirements have been submitted to the Office of Management and Budget (OMB) for review. The information collected will consist of initial and supplemental plans for cigarette packages and advertisements submitted to FDA for a total estimated one-time reporting burden of 11,100 hours. FDA expects 59 respondents to submit initial plans and 30 respondents to submit supplements. In addition to the one-time reporting requirement, FDA also expects an annual recordkeeping burden of 267 hours and a total of 59 record keepers. FDA estimates these information collections to result in a total burden of 11,367 hours.

Statutory authorization for the rule

FDA promulgated this final rule pursuant to the section 1333 of title 15 United States Code; sections 371, 374, 387c, 387e, and 387i, of title 21 United States Code; in addition to sections 201 and 202 of Public Law 111-31.

Executive Order No. 12,866 (Regulatory Planning and Review)

FDA determined that this final rule is economically significant.

Executive Order No. 13,132 (Federalism)

FDA determined that this final rule does not have federalism implications as FDA asserted it will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.