



Office of the General Counsel

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September 12, 1996

The Honorable Nancy Landon Kassebaum
Chairman
The Honorable Edward M. Kennedy
Ranking Minority Member
Committee on Labor and Human Resources
United States Senate

The Honorable Thomas J. Bliley, Jr.
Chairman
The Honorable John D. Dingell
Ranking Minority Member
Committee on Commerce
House of Representatives

Subject: Department of Health and Human Services, Food and Drug
Administration: Regulations Restricting the Sale and Distribution of
Cigarettes and Smokeless Tobacco to Protect Children and Adolescents

Pursuant to section 801(a)(2)(A) of title 5, United States Code, this is our report on a major rule promulgated by Department of Health and Human Services, Food and Drug Administration, entitled "Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents" (RIN: 0910-AA48). We received the rule on August 26, 1996. It was published in the Federal Register as a final rule on August 28, 1996. 61 Fed. Reg. 44395.

The rule prohibits the sale of nicotine-containing cigarettes and smokeless tobacco to individuals under the age of 18; requires manufacturers, distributors, and retailers to comply with various conditions regarding the sale and distribution of these products; requires retailers to verify a purchaser's age by photographic identification; prohibits all free samples; limits the distribution of these products through vending machines and self-service displays by permitting such methods of sale only in facilities where access by individuals under 18 is prohibited; limits the advertising and labeling to which children and adolescents are exposed; prohibits promotional, non-tobacco items such as hats and tee shirts; prohibits sponsorship of

sporting and other events, teams and entries in the brand name of tobacco products; and requires manufacturers to provide intended use information on all cigarette and smokeless tobacco product labels and in cigarette advertising.

The rule is predicated on the Food and Drug Administration's assertion of jurisdiction under the Federal Food, Drug and Cosmetic Act over cigarettes and smokeless tobacco as delivery devices for nicotine. The lengthy jurisdictional determination was published in the Federal Register on August 28, 1996, as an annex to the final rule.

The rule will become effective 1 year from the date of publication in the Federal Register except that the prohibition regarding sale to any person younger than 18 years of age and the requirement for photographic identification to verify the age of purchasers will become effective 6 months after publication. The restriction on event sponsorship and manufacturers' compliance with existing device registration and listing requirements and good manufacturing practice requirements will become effective 2 years from publication.

Enclosed is our assessment of the Food and Drug Administration's compliance with the procedural steps required by sections 801(a)(1)(B)(i) through (iv) of title 5 with respect to the rule. Our review indicates that the Administration complied with the applicable requirements.

If you have any questions about this report, please contact James W. Vickers, Senior Attorney, at (202) 512-8210. The official responsible for GAO evaluation work relating to the Department of Health and Human Services, Food and Drug Administration is Sarah F. Jaggar, Director, Health Services, Quality and Public Health Issues. Ms. Jaggar can be reached at (202) 512-7119.

Robert P. Murphy
General Counsel

Enclosure

cc: The Honorable Donna E. Shalala
The Secretary of Health and Human Services

ANALYSIS UNDER 5 U.S.C. §§ 801(a)(1)(B)(i)-(iv) OF A MAJOR RULE
ISSUED BY
THE DEPARTMENT OF HEALTH AND HUMAN SERVICES, FOOD AND DRUG
ADMINISTRATION
ENTITLED
"REGULATIONS RESTRICTING THE SALE AND DISTRIBUTION OF CIGARETTES
AND SMOKELESS TOBACCO TO PROTECT CHILDREN AND ADOLESCENTS"
(RIN: 0910-AA48)

(i) Cost-benefit analysis

An analysis of the costs and benefits of the rule was conducted by the Food and Drug Administration (FDA) and published in the notice of proposed rulemaking on August 11, 1995, and is contained in the preamble to the final rule. The analysis in the final rule has been revised based on comments the FDA received and now also considers the costs and benefits associated with a rule issued by the Substance Abuse and Mental Health Services Administration (SAMHSA) on January 19, 1996, governing a program of State-operated enforcement activities to restrict the sale or distribution of tobacco products to individuals under the age of 18. FDA considers the two rules complementary and cannot separately quantify the benefits of the two programs and since both rules work collectively to reduce youth access to tobacco products, the costs attributable to the SAMHSA program are included in the analysis.

The analysis based its benefits on achieving the "Healthy People 2000," a Department program, goal of reducing underage tobacco use by one-half in order to prevent over 60,000 early deaths. The analysis places a monetary value of these health benefits (at a 3 percent discount rate) at an estimated \$28 to \$43 billion per year, including \$2.6 billion in medical cost savings, \$900 million in productivity gains from reduced morbidity and \$24.6 to \$39.7 billion per year in willingness-to-pay values for averting premature fatalities. The analysis states that if the 50 percent reduction in underage tobacco use is not reached and only 5 percent of the 1 million adolescents who become new smokers are deterred, the annual benefits would be \$2.8 to \$4.3 billion per year.

FDA estimates the overall compliance costs of the rule to be from \$174 million to \$187 million in one-time costs and \$149 million to \$185 million in annual operating costs. These costs will be borne by manufacturers (\$78 to \$91 million in one-time costs and \$2 million in annual costs), retail establishments (\$96 million in one-time costs and \$78 million in annual costs), FDA (\$3 to \$5 million in enforcement costs per year) and State governments (\$25 to \$50 million per year in administering various SAMHSA enforcement programs).

FDA recognizes that it could not quantify every regulatory cost because of significant distributional and transitional effects of the rule. For example, lost sales experienced by suppliers of advertising were considered distributional impacts because the dollars not spent on advertising are not lost to the economy but will be spent on other goods and services. Also, if State and Federal excise taxes remain at the current levels, tax revenues will decrease over time because of decreased sales.

In conclusion, the analysis finds that while compliance with the rule will bring significant health benefits to the population and also exact long-term revenue losses on the tobacco industry and short-term costs on various affiliated industry sectors, the benefits of the rule will greatly exceed the compliance costs on the United States economy.

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

The FDA has concluded that the rule will have a significant economic impact on a substantial number of small entities and an initial regulatory flexibility analysis and final regulatory flexibility analysis have been prepared and included in the notice of proposed rulemaking and the final rule notice, respectively, as required by sections 603 and 604. The analyses comply with the informational requirements of the sections including the classes of small entities subject to the rule and alternatives considered to reduce the burden on the small entities.

The final analysis discusses the FDA's decision not to exempt small entities from the rule because an exemption for small retailers would shift underage sales to those locations, lessening or eliminating the effectiveness and benefits of the access restrictions. However, a total ban on vending machines and direct mail order sales have been deleted from the final rule because of their impact on small entities.

The analyses use both quantifiable and general descriptions of the effects of the rule on small entities as required by section 607 and numerous small entities participated in the rulemaking as required by section 609 by submitting comments on the proposed regulation following the inclusion in the notice of proposed rulemaking of the initial regulatory flexibility analysis which discussed the economic impact on small entities.

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

Based on the cost-benefit analysis performed by FDA, the rule will impose an unfunded mandate on the private sector of over \$100 million annually and therefore the rule is subject to the requirements of the Act.

As required by section 205, FDA considered regulatory alternatives to the requirements of the rule but determined that the provisions of the final rule constituted the most cost-effective and least burdensome alternative that would meet the objective of the rule.

The FDA rejected the regulatory alternative of a total ban on all tobacco advertising. Also, a more prescriptive requirement for manufacturers to monitor the sales and distribution of retail establishments was not imposed because it would have imposed an additional cost of \$85 million per year. Finally, a requirement to include package inserts containing educational information in cigarette and smokeless tobacco was not chosen because the FDA was not certain the benefits would justify the compliance costs.

Section 204 requires that State, local and tribal governments have an opportunity for input and numerous comments were received from State and local governments, health departments, substance abuse programs and law enforcement agencies. These comments were reviewed and considered as discussed in the preamble to the final rule.

(iv) Other relevant information or requirements under Acts and Executive orders

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

The FDA promulgated the rule under the notice and comment procedures of 5 U.S.C. § 553 and its own agency regulation regarding the promulgation of regulations found at section 10.40 of Title 21 of the Code of Federal Regulations.

On August 11, 1995, the proposed rule was published in the Federal Register (60 Fed. Reg. 41314) and in the same issue, a document entitled "Analysis Regarding The Food And Drug Administration's Jurisdiction Over Nicotine-Containing Cigarettes And Smokeless Tobacco Products" was published and comments were requested. 60 Fed. Reg. 41453. The comment period, following an extension, remained open for 144 days. In the months that followed the publication of the proposed rule and during the comment period, the FDA made available to the public over 200,000 pages of documents which were cited by the agency or considered in the promulgation of the rule.

The FDA received over 700,000 comments in response to the proposed rule. While the FDA reports many of the comments were form letters, there were over 95,000 distinct or unique comments filed with the FDA.

The preamble to the final rule discusses many of the comments received and the action taken by the agency in response or why the comments did not change the agency's position.

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

The proposed rule contained information collections which would have required the manufacturers and retailers of cigarettes and smokeless tobacco to use established names for cigarettes and smokeless tobacco products, establish and maintain educational programs, observe certain formats and content requirements for labeling and advertising and the submission of labels, labeling and advertising to the FDA. The FDA solicited comments on the above information collections including among other information, the necessity of the collection, the accuracy of the estimated burden and ways to enhance the information collection.

Following the receipt and evaluation of the comments, the FDA has revised certain burden estimates and has deleted the requirement for the submission of labeling to the FDA and the establishment of educational programs.

The information collections in the proposed rule were approved by the Office of Management and Budget under OMB No. 0910-0312. Because of the above noted changes to the collections, FDA has resubmitted the matter to OMB for review and approval and prior to the effective date of the rule, FDA will publish a notice in the Federal Register of OMB's action on the provisions.

Statutory authorization for the rule

The FDA has cited sections 502, 510, 518, 519, 520, 701, 704 and 903 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. §§ 352, 360, 360h, 360i, 360j, 371, 374 and 393) as authority for the rule and in particular, the device provisions of the Act, including the restricted device authority in section 520(e) of the Act. 21 U.S.C. § 360j(e).

Executive Order No. 12866

The rule was determined to be a "significant regulatory action" under Executive Order No. 12866 requiring review by the Office of Management and Budget, Office of Information and Regulatory Affairs (OIRA). OIRA approved the final rule on August 22, 1996, as complying with the requirements of the Order based on the information supplied by FDA, including a planned regulatory action document

describing the reason for the rule and an assessment of the costs and budgetary impact of the rule.

Executive Order No. 12606 (Family)

FDA considered whether the rule would have a significant impact on family formation, maintenance and general well-being as required by the Order and found that the rule would not have a negative impact in these areas. In the preamble to the proposed rule, it was noted that the rule would help the significant majority of families that seek to discourage their children from using cigarettes and smokeless tobacco. 60 Fed. Reg. 41356. FDA responds in the preamble to the final rule to several comments it received and maintains its conclusion that the rule does not have a negative impact.

Executive Order No. 12612 (Federalism)

The rule was reviewed by the FDA under the Order which requires Federal agencies to examine regulatory actions to determine if they have a significant impact on the States, on the relationship between the States and the Federal government, and on the distribution of power and responsibilities among the various levels of government. In the preamble to the final rule, the FDA addresses the various issues raised by commenters in this area, including the preemption of State and local laws which are different from or in addition to the requirements under the final rule; whether there is an infringement on the States' right to regulate tobacco and businesses within the State and protect the health of its citizens; the allocation of a State's resources and the rule's possible impact on the States' economies. The FDA concludes that the preemptive effects of the final rule are consistent with the Order.

Executive Order No. 12630 (Property Rights)

The FDA reviewed the rule under the Order and concluded that the affect of the final rule would not constitute a "taking" of private property. The preamble to the final rule discusses issues raised by various commenters in the areas of the use of self-service displays, vending machines, restrictions on sponsorship of events except in the corporate name and loss of employment and maintains its conclusion that there would be no "taking" under the Order. The FDA's position is that reductions in personal property's value, even prohibitions on all economically viable uses, and financial expenditures to comply with a regulatory requirement do not necessarily establish a taking, citing various court decisions for support.

The FDA did not identify any other statute or executive order imposing procedural requirements relevant to the rule.