U.S. GOVERNMENT ACCOUNTABILITY OFFICE

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

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December 6, 2023

The Honorable Bernard Sanders
Chairman
The Honorable Bill Cassidy
Ranking Member
Committee on Health, Education, Labor, and Pensions
United States Senate

The Honorable Cathy McMorris Rodgers
Chair
The Honorable Frank Pallone, Jr.
Ranking Member
Committee on Energy and Commerce
House of Representatives

Subject: *Department of Health and Human Services, Food and Drug Administration: Direct-to-Consumer Prescription Drug Advertisements: Presentation of the Major Statement in a Clear, Conspicuous, and Neutral Manner in Advertisements in Television and Radio Format*

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 "Direct-to-Consumer Prescription Drug Advertisements: Presentation of the Major Statement in a Clear, Conspicuous, and Neutral Manner in Advertisements in Television and Radio Format" (RIN: 0910-AG27). We received the rule on November 28, 2023. It was published in the *Federal Register* as a final rule on November 21, 2023. 88 Fed. Reg. 80958. The effective date is May 20, 2024.

According to FDA, the final rule amends its regulations concerning direct-to-consumer (DTC) advertisements (ads) for human prescription drugs presented in television or radio format and stating the name of the drug and its conditions of use (DTC TV/radio ads). Specifically, FDA stated the final rule implements a requirement of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, added by the Food and Drug Administration Amendments Act of 2007 (FDAAA), 21 U.S.C. § 301 note, that in such DTC TV/radio ads, the major statement relating to side effects and contraindications must be presented in a clear, conspicuous, and neutral manner. As directed by FDAAA, FDA stated it is establishing standards to determine whether the major statement in DTC TV/radio ads is presented in a clear, conspicuous, and neutral manner.

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.

Shirley A. Jones
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Enclosure

cc: Nnaemeka Chukwudebe
Regulatory Policy Analyst, RPMS
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ENCLOSURE

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
"DIRECT-TO-CONSUMER PRESCRIPTION DRUG ADVERTISEMENTS:
PRESENTATION OF THE MAJOR STATEMENT IN A CLEAR, CONSPICUOUS, AND
NEUTRAL MANNER IN ADVERTISEMENTS IN TELEVISION AND RADIO FORMAT"
(RIN: 0910-AG27)

(i) Cost-benefit analysis

The Department of Health and Human Services, Food and Drug Administration (FDA) estimated the total present value of costs of the final rule over a 10-year time horizon ranges from $104.8 million to $331.8 million, with a primary estimate of $218.3 million, at a 7 percent discount rate; the present value ranges from $123.8 million to $393.0 million, with a primary estimate of $258.4 million, at a 3 percent discount rate. FDA further estimated the benefits of this final rule stem from and include helping consumers notice, attend to, and understand the major statement in direct-to-consumer advertisements. FDA further stated the standards in the final rule help to ensure that direct-to-consumer advertisements convey a truthful and non-misleading net impression about the advertised drug and help ensure that consumers are better informed when they participate in healthcare decision making.

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

FDA determined the final rule would create a significant economic impact on a substantial number of small entities.

(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 will not have an effect on state, local, or tribal governments, in the aggregate, or on the private sector, of $177 million ($100 million, adjusted for inflation) or more in any one year.

(iv) Agency actions relevant to the Administrative Pay-As-You-Go-Act of 2023, Pub. L. No. 118-5, div. B, title III, 137 Stat 31 (June 3, 2023)

Section 270 of the Administrative Pay-As-You-Go-Act of 2023 amended 5 U.S.C. § 801(a)(2)(A) to require GAO to assess agency compliance with the Act, which establishes requirements for administrative actions that affect direct spending, in GAO's major rule reports. In guidance to Executive Branch agencies, issued on September 1, 2023, the Office of Management and Budget (OMB) instructed that agencies should include a statement explaining that either: "the Act does not apply to this rule because it does not increase direct spending; the Act does not apply to this rule because it meets one of the Act's exemptions (and specifying the relevant exemption); the OMB Director granted a waiver of the Act's requirements pursuant to section 265(a)(1) or (2) of the Act; or the agency has submitted a notice or written opinion to the

OMB Director as required by section 263(a) or (b) of the Act" in their submissions of rules to GAO under the Congressional Review Act. OMB, *Memorandum for the Heads of Executive Departments and Agencies,* Subject: Guidance for Implementation of the Administrative Pay-As-You-Go Act of 2023, M-23-21 (Sept. 1, 2023), at 11–12. OMB also states that directives in the memorandum that supplement the requirements in the Act do not apply to proposed rules that have already been submitted to the Office of Information and Regulatory Affairs, however agencies must comply with any applicable requirements of the Act before finalizing such rules.

In its submission to us, FDA did not discuss the Act.

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

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

On March 29, 2010, FDA published a proposed rule. 75 Fed. Reg. 15376. FDA received over 70 comments on the proposed rule from consumers, public interest or consumer groups, trade and industry associations, healthcare providers, and drug firms. FDA responded to the comments in the final rule.

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

FDA determined the final rule contains information collection requirements (ICRs) subject to PRA. The ICRs are entitled "Prescription Drug Advertisements" and are associated with OMB Control Number 0910-0686. FDA estimated the burden of the ICRs to be 3567.5 hours.

Statutory authorization for the rule

FDA promulgated the final rule pursuant to sections 321, 331, 352, 355, 360b, and 371 of title 21, United States Code.

Executive Order No. 12866 (Regulatory Planning and Review)

FDA stated the final rule had been reviewed by OMB which determined it was not significant.

Executive Order No. 13132 (Federalism)

FDA determined the final rule does not contain polices that have federalism implications.