U.S. GOVERNMENT ACCOUNTABILITY OFFICE

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Washington, DC 20548

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May 20, 2024

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: Medical Devices; Laboratory Developed Tests*

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 "Medical Devices; Laboratory Developed Tests" (RIN: 0910-AI85). We received the rule on April 30, 2024. It was published in the *Federal Register* as a final rule on May 6, 2024. 89 Fed. Reg. 37286. The effective date of the rule is July 5, 2024.

This final rule amends FDA regulations to make explicit that in vitro diagnostic products (IVDs) are devices under the Federal Food, Drug, and Cosmetic Act (FD&C Act) including when the manufacturer of the IVD is a laboratory. In conjunction with this amendment, FDA is phasing out its general enforcement discretion approach for laboratory developed tests so that IVDs manufactured by a laboratory will generally fall under the same enforcement approach as other IVDs.

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 Charlie McKiver, Assistant General Counsel, at (202) 512-5992.

Shirley A. Jones
Managing Associate General Counsel

Enclosure

cc: Samuel A. Shipley
Senior Policy & Regulatory Coordinator
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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
"MEDICAL DEVICES; LABORATORY DEVELOPED TESTS"
(RIN: 0910-AI85)

(i) Cost-benefit analysis

The Food and Drug Administration (FDA) conducted an economic analysis of this final rule. FDA estimated that the annual benefits over 20 years range from $0.99 billion to $11.1 billion at a 7 percent discount rate, with a primary estimate of $3.51 billion, and from $1.24 billion to $13.62 billion at a 3 percent discount rate, with a primary estimate of $4.34 billion. The analysis included a quantification of benefits to patients from averted health losses due to problematic in vitro diagnostic products (IVDs) offered as laboratory developed tests (LDTs), with a particular focus on certain broad disease categories associated with the majority of misdiagnosis-related harms in the United States. FDA stated that additional benefits included averted non-health losses from reduced spending on problematic IVDs offered as LDTs and unquantified reduction in costs from lawsuits.

According to FDA, the annualized costs of the rule range from $566 million to $3.56 billion at a 7 percent discount rate, with a primary estimate of $1.29 billion, and from $603 million to $3.79 billion at a 3 percent discount rate, with a primary estimate of $1.37 billion. FDA stated that it quantified costs to affected laboratories for complying with statutory and regulatory requirements, as well as costs to the agency.

(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 is likely to impose 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 estimated that this final rule will result in an expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more, adjusted annually for inflation, in any one year. FDA analyzed the estimated benefits, costs, transfers, and effects of the rule and developed an Economic Analysis of Impacts that assesses the impacts of the phaseout policy.

(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.

FDA did not discuss the Act in this final rule. In its submission to us, FDA stated that the Act does not apply to the rule because it does not increase direct spending.

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

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

On October 3, 2023, FDA published a proposed rule. 88 Fed. Reg. 68006. FDA received more than 6,500 comments on the proposed rule from a variety of entities, including medical device associations, members of the medical device and pharmaceutical industries, medical and healthcare professional associations, hospitals and academic medical centers, accreditation organizations, other advocacy organizations, government agencies, and individuals. FDA responded to comments in this final rule.

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

FDA determined that this final rule contains no information collection requirements under the Act. FDA noted that it expected that the phaseout of its general enforcement discretion approach for LDTs will necessitate adjustment to the burden estimates for several approved information collections, before the relevant phaseout stage begins.

Statutory authorization for the rule

FDA promulgated this final rule pursuant to sections 201(h)(1), 301, 501, 502, 510, 513, 514, 515, 518, 519, 520, 701, 702, 704, and 801 of the Federal Food, Drug, and Cosmetic Act, and section 351 of the Public Health Service Act. *See* sections 321(h)(1), 331, 351, 352, 360, 360c, 360d, 360e, 360h, 360i, 360j, 371, 372, 374, and 381 of title 21; and section 262 of title 42, United States Code.

Executive Order No. 12866 (Regulatory Planning and Review)

FDA determined that this final rule is significant under the Order and submitted it to the Office of Information and Regulatory Affairs for review.

Executive Order No. 13132 (Federalism)

FDA determined that this final rule does not have federalism implications. FDA stated that the rule does not contain policies that 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.