

FOR PUBLICATION

In the  
United States Court of Appeals  
For the Eleventh Circuit

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No. 24-12446

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JESSICA PALACIO,

*Petitioner,*

*versus*

U.S. FOOD AND DRUG ADMINISTRATION,

*Respondent.*

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Petition for Review of a Decision of the  
Food and Drug Administration  
Agency No. FDA-2023-N-0201

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Before WILLIAM PRYOR, Chief Judge, and BRASHER and ABUDU, Circuit Judges.

WILLIAM PRYOR, Chief Judge:

This petition for review requires us to decide whether a Food and Drug Administration debarment order was contrary to

law or arbitrary and capricious. *See* 5 U.S.C. § 706(2)(A). Jessica Palacio was convicted of making a false statement to the Administration during an investigation. The Administration then debarred her under a statute requiring permanent debarment for individuals “convicted of a felony under Federal law for conduct . . . relating to the development or approval, including the process for development or approval, of any drug product.” 21 U.S.C. § 335a(a)(2). Because the Administration’s debarment order was required by law, we deny the petition for review.

### I. BACKGROUND

Jessica Palacio worked as a clinical trial coordinator for Unlimited Medical Research, LLC, from 2013 to 2015. Unlimited conducted a clinical trial for a pharmaceutical company to evaluate an asthma drug for pediatric use. The company terminated the clinical trial in 2015 and alerted the Food and Drug Administration to irregularities in the data, including a record stating that Palacio screened a child while school attendance records established that the child was in school.

The Administration initiated an investigation in early 2017. Palacio signed an affidavit confirming that she conducted the screening of the child. Her sworn statement was false because she knew the child did not participate in the clinical trial. A jury found Palacio guilty of one count of making a false statement to the Administration, *see* 18 U.S.C. § 1001(a)(2), and the district court sentenced her to 36 months of imprisonment.

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The Administration permanently debarred Palacio from providing services relating to drug applications based on her false-statement conviction. *Jessica Palacio; Denial of Hearing; Final Debarment Order*, 89 Fed. Reg. 46,125 (May 28, 2024). The Administration invoked a statute that requires it to permanently debar individuals “convicted of a felony under Federal law for conduct . . . relating to the development or approval, including the process for development or approval, of any drug product.” 21 U.S.C. § 335a(a)(2). It explained that the phrase “‘relating to the development or approval’ . . . encompasses all things that are logically connected with the development or approval of a drug product,” which necessarily includes investigations. And it declined to “address Palacio’s . . . efforts to distinguish her own conduct from that of other debarred individuals” because Palacio’s conduct satisfied the “clear language” of the statute.

## II. STANDARDS OF REVIEW

Under the Administrative Procedure Act, we must “hold unlawful and set aside agency action, findings, and conclusions” that are “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” 5 U.S.C. § 706(2). We “exercise [our] independent judgment in deciding whether an agency has acted within its statutory authority.” *Loper Bright Enters. v. Raimondo*, 144 S. Ct. 2244, 2273 (2024). But “[a]rbitrary-and-capricious review is deferential—an agency’s decisions need only be reasonable and reasonably explained.” *Fla. Agency for Health Care Admin. v. Adm’r for Ctrs. for Medicare & Medicaid Servs.*, 161 F.4th 765, 786 (11th Cir. 2025) (citation and internal quotation marks omitted).

### III. DISCUSSION

The Administration must permanently debar individuals it “finds . . . ha[ve] been convicted of a felony under Federal law for conduct . . . relating to the development or approval, including the process for development or approval, of any drug product.” 21 U.S.C. § 335a(a)(2). To interpret this law, “we begin with the statutory text, and proceed from the understanding that unless otherwise defined, statutory terms are generally interpreted in accordance with their ordinary meaning” at “the time of enactment.” *Regions Bank v. Legal Outsource PA*, 936 F.3d 1184, 1190 (11th Cir. 2019) (citation and internal quotation marks omitted). The ordinary meaning of the text resolves this appeal.

Palacio’s false statement relates to the drug development and approval process because it impeded an investigation into the integrity of that very process. “Relate to” means “[t]o stand in some relation; to have bearing or concern; to pertain; refer; to bring into association with or connection with.” *Relate*, BLACK’S LAW DICTIONARY (6th ed. 1990); *see also Relate*, WEBSTER’S THIRD NEW INT’L DICTIONARY 1916 (1993) (“to be in relationship: have reference”); *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 384 (1992) (defining “relates to” as “ha[ving] a connection with or reference to” (citation and internal quotation marks omitted)). The ordinary meaning of “relating to” “is a broad one.” *Morales*, 504 U.S. at 383 (internal quotation marks omitted). Indeed, “[i]t is hard . . . to think of a more capacious term to use in defining the coverage of a provision.” *AQuate II LLC v. Myers*, 100 F.4th 1316, 1321 (11th Cir. 2024).

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Palacio argues that her false-statement conviction does not relate to drug development or approval because she did not make the false statement until April 2017, “almost [two] years after” the pharmaceutical company terminated the clinical trial. But the ordinary meaning of “relating to” contains neither a temporal nor a causal limitation. And section 335a covers conduct relating to “the *process* for development or approval,” not just the development or approval of a specific drug. 21 U.S.C. § 335a(a)(2)(A) (emphasis added).

She also argues her debarment is arbitrary and capricious because the false statements underlying other debarments were made “while a clinical trial or similar study was ongoing.” But even if typical debarments occur while clinical trials are ongoing, Palacio’s conduct satisfied the plain language of the statute, so her debarment was not arbitrary or capricious. *See BBX Cap. v. FDIC*, 956 F.3d 1304, 1317 (11th Cir. 2020).

#### IV. CONCLUSION

We **DENY** the petition for review.