NO. 19-152

In the
Supreme Court of the United States

AMARIN PHARMA, INC.,
AMARIN PHARMACEUTICALS IRELAND, LTD.,

PETITIONERS,

v.

INTERNATIONAL TRADE COMMISSION, ET AL.,

RESPONDENTS.

On Petition for a Writ of Certiorari to the U.S. Court of Appeals for the Federal Circuit

REPLY BRIEF FOR PETITIONERS

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REPLY BRIEF

The arguments advanced by the government and private respondents underscore the importance of the question presented. Respondents cannot dispute that the decision below eliminates private rights of action that Congress granted in the Tariff Act of 1930, depriving manufacturers of any remedy for industry-threatening unfair trade practices when they involve imported products that are also subject to regulation under the Food, Drug and Cosmetic Act ("FDCA"). In fact, respondents embrace that result, arguing that the International Trade Commission's obligations under the Tariff Act to investigate unfair trade practices should be subordinate to FDA's exercise of enforcement discretion under the FDCA. But their arguments cannot be reconciled with the Tariff Act's plain text, the reasoning of *POM Wonderful LLC v. Coca-Cola Co.*, 573 U.S. 102 (2014), or basic principles of administrative law. The decision below deepens a circuit split. It also raises important questions concerning whether one agency's discretion not to enforce a statute can suspend a different agency's obligations to enforce a different statute over which the first agency has no authority. The Court should grant review.

I. The Court Should Grant Review to Restore the Private Right of Action That Congress Created In the Tariff Act.

Because the Federal Circuit has exclusive jurisdiction to review Commission determinations, *see* 19 U.S.C. § 1337(c); 28 U.S.C. § 1295(a)(6), absent certiorari the decision below will be the final

say on the Tariff Act's meaning and the Commission's obligations to investigate unfair trade practices involving FDA-regulated products. The results of eliminating that remedy will have far-reaching consequences for our nation's economy and the many manufacturers whose products are subject to regulation under the FDCA. Respondents cannot deny that FDA has no authority to protect domestic industry from unfair trade. Nor do they deny that FDA lacks the resources to police the advertising of tens of thousands of products that make up the $40 billion dietary-supplement industry.

Respondents nonetheless assert that review is unwarranted because Congress intended the Commission's Tariff Act obligations to be subservient to FDA's enforcement discretion. In their view, because the United States has exclusive authority to enforce FDCA violations, 21 U.S.C. § 337(a), the Commission is barred from investigating unfair trade practices until FDA has determined that a product is deceptively advertised. But *POM Wonderful* rejected that argument: the "[c]entralization of FDCA enforcement authority in" FDA "does not indicate that Congress intended to foreclose private enforcement of other federal statutes." 573 U.S. at 117.

Respondents contend that this case is distinguishable because Amarin's claims require understanding the meaning of terms defined in the FDCA, which respondents argue makes the claims "purely derivative" of an FDCA violation. U.S. Opp. 12. Respondents are wrong. Amarin is not seeking to enforce the FDCA or requesting a remedy under that statute. Nor do its claims exist "solely by virtue

of the FDCA." U.S. Opp. 12 (quoting *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4, 352 (2001)). Amarin's claims exist because of the rights and obligations Congress created in the Tariff Act, which requires the Commission to investigate alleged unfair trade practices, and because of the duties imposed by the Lanham Act, which prohibits false and misleading advertising. That importers' unfair trade practices might also constitute an unenforced FDCA violation does not suspend the Commission's obligations under the Tariff Act. If Congress tomorrow were to eliminate any obligation under the FDCA for products to be properly labeled as "drugs" or "dietary supplements" *see* 21 U.S.C. §§ 343, 352(a), (n), 355(a), that would not change what it means for a product to be a drug as opposed to a dietary supplement. Nor would it eliminate the competitive injuries caused by importers that are deceptively advertising their products, or Congress's intent that the Commission would protect domestic industry from competitive injuries caused by unfair trade.

Where, as a here, a party asserts that one statute "displaces" other statutes, it "bears the heavy burden of showing 'a clearly expressed congressional intention' that such a result should follow." *Epic Sys. Corp. v. Lewis*, 138 S. Ct. 1612, 1624 (2018) (citation omitted). Respondents have not met that burden. They cite no provision establishing that Congress intended to prevent claims under the Tariff Act from being cognizable until FDA takes enforcement action under the FDCA. In fact, Congress expressed the opposite intent. The Tariff Act mandates that the

Commission "shall" investigate when presented with a "complaint under oath" and instructs that other agencies must "cooperate fully" in those investigations, including providing the Commission with "all records, papers, and information" relevant to the investigation's "subjects." 19 U.S.C. §§ 1334, 1337(b)(1). The statute also directs that when the Commission finds that unfair trade practices exist, it must deal with them "in addition to any other provision of law." *Id.* § 1337(a)(1).

Like the Federal Circuit's decision, respondents fail to account for the statute's plain language. Respondents note that the Commission's authority to consult with other agencies applies only "in appropriate matters" and that its obligation to deal with unlawful trade practices does not "define the circumstances in which the Commission must or should determine whether a violation has occurred." U.S. Opp. 16. But that misses the point. The Tariff Act makes clear that, when presented with a complaint, the Commission "*shall* investigate," 19 U.S.C. § 1337(b)(1) (emphasis added), and "*shall* determine" with respect to "each investigation" whether a violation has occurred, *id.* § 1337(c) (same), and that other agencies "*shall* cooperate fully" in the Commission's investigation, *id.* § 1334 (same). Those obligations are mandatory, *see Kingdomware Techns., Inc. v. United States*, 136 S. Ct. 1969, 1977 (2016) ("shall" "imposes a mandatory duty"), and are not subordinated to other statutory provisions except as expressly provided by Congress, *see* 21 U.S.C. § 1337(b)(3) (precluding the Commission from investigating antidumping

violations). In short, the Tariff Act has no carve out for products subject to regulation under the FDCA.

Nor would enforcing the Tariff Act interfere with FDA's judgment or intrude on FDA's prerogatives. *See* U.S. Opp. 12; Priv. Opp. 26–27. As the petition explains, FDA does not pre-classify or pre-approve products as dietary supplements rather than drugs. Instead, it issues generally applicable rules and guidance interpreting the statutory definitions so manufacturers can decide for themselves whether a product qualifies as a drug or a dietary supplement. The regulatory scheme depends on the requirements being clear enough for manufacturers to know how to label their products.

Contrary to private respondents' suggestion, there is no "technical review" by FDA or "public comment process" that takes place before a manufacturer markets its products. Priv. Opp. 28. Amarin's complaint asks the Commission to do nothing more than what manufacturers are expected to do on their own. Moreover, if there is any question as to what existing law requires—or the status or meaning of future guidance that FDA may or may not issue—the Tariff Act's provisions instruct the Commission to coordinate with FDA and requires FDA to "cooperate fully." 19 U.S.C. § 1334. The required cooperation surely obliges FDA to "furnish" the Commission with the existing rules, regulations, and guidance that inform market understandings as to when a product qualifies as a drug or a dietary supplement. *Id.*

Private respondents speculate that FDA might at some point issue new guidance, perhaps in

response to a citizen petition. Priv. Opp. 4. But the government does not make any commitment and, at oral argument below, private respondents' counsel asserted that future guidance would have no effect on this case because it would not address the specific issues raised. *See Amarin Pharma, Inc. v. U.S. Int'l Trade Comm'n*, No. 2018-1247, at 44:00–46:15 (argued June 8, 2018). In any event, the possibility that FDA may or may not take future action only highlights the problems with the Federal Circuit's decision. More than a decade of existing rules, guidance, and warning letters has already clarified the statutory distinction between drugs and dietary supplements. Under existing law, it is clear that importers are falsely labeling and deceptively advertising their products as (or for use in) dietary supplements. New guidance may reinforce existing law—or even attempt to modify it—but that does not change the Commission's obligation to investigate unfair trade practices when they are brought to its attention. The problem is not that the Commission has concluded that Amarin's claims lack merit under existing law; the problem is that it has refused even to consider them on the misguided view that the obligations imposed by the Tariff Act are suspended until FDA takes enforcement action under the FDCA. That legal question is worthy of this Court's review.

II. The Federal Circuit's Decision Deepens A Split Among the Lower Courts.

Granting certiorari would also allow the Court to resolve a circuit split over the proper interpretation of *POM Wonderful*. In the Second Circuit, "a Lanham Act claim is not precluded by

FDA regulation under the FDCA because the two statutes serve distinct and complementary purposes," even if the Lanham Act claim is contrary to an affirmative decision made by FDA. *Church & Dwight Co. v. SPD Swiss Precision Diagnostics, GmbH*, 843 F.3d 48, 63, 65 (2d Cir. 2016). In contrast, in the Eleventh Circuit, a Lanham Act claim is permissible only if a court does not have to interpret or apply the FDCA, regardless of any action taken by FDA. *Hi-Tech Pharms., Inc. v. HBS Int'l Corp.*, 910 F.3d 1186, 1199 (11th Cir. 2018).

Respondents cannot deny that the courts of appeals are splintered and that this confusion extends to the district courts. *See* Pet. 31; *Frtompovicz v. Niagara Bottling, LLC*, 313 F. Supp. 3d 603, 616 (E.D. Pa. 2018). They instead downplay the split, arguing that Amarin's reliance on *Church & Dwight* is "misplaced" because that case did not require considering the meaning of terms defined in the FDCA. U.S. Opp. 16–17. But that misunderstands the decision's rationale.

In *Church & Dwight*, FDA made an affirmative judgment that a product satisfied the FDCA's labeling requirements in a situation where (unlike here) the agency pre-approved the product for sale. Even still, the Second Circuit held that the plaintiff could pursue a Lanham Act claim: "The fact that the FDA has satisfied itself that a product's labeling is sufficiently accurate to secure FDA approval gives no assurance that the intervention of a competitor would not reveal problematic misleading messaging that is harmful to the competitor's interests, which the federal agency either overlooked or failed to appreciate as important." 843 F.3d at 63. According

to the Second Circuit, "FDA approval is no substitute for the intervention of a competitor, which by dint of its 'market expertise' is uniquely qualified to 'provide incentives for manufacturers to behave well.'" *Id.* (quoting *POM Wonderful*, 573 U.S. at 115).

It is not possible to reconcile that approach with the approach taken by the Federal Circuit (or by the Eleventh Circuit). Amarin's position here is much stronger than the plaintiff's in *Church & Dwight*, because Amarin is not seeking a judgment that is inconsistent with any FDA determination. In this case, FDA has never determined whether importers' products are properly labeled. Nor has it ever approved the products. FDA has merely declined to exercise its enforcement authority. A failure to enforce is not an affirmative action with the force of law that could displace or suspend other statutory obligations. FDA's failure to restrain a violation of the FDCA does not mean that it has exempted the underlying conduct from other legal requirements—let alone other legal requirements that, like the Tariff Act, FDA has no authority to administer.

It is unsurprising that the lower courts are confused given the government's ever-shifting positions, which is another reason to grant review. In *POM Wonderful*, the government argued that Lanham Act claims "are not precluded by the mere fact that the FDCA covers a product generally, but are precluded in situations where the FDCA or the FDA, through its regulations, have 'specifically require[d] or authorize[d]' a challenged aspect of a label." *Church & Dwight*, 843 F.3d at 63 (quoting the government's brief). Under that approach,

which *POM Wonderful* rejected as too restrictive, Amarin's Tariff Act claims would be allowed to proceed. In this case, however, the government has taken an even more extreme position, convincing the Federal Circuit that claims could proceed only if FDA first determines that the products are misbranded: "Without sufficient guidance from the FDA, the Commission cannot adjudicate Amarin's claims." Br. for Appellee ITC at 17, No. 18-1247, Dkt. 62 (Mar. 19, 2018).

III. This Case Is an Ideal Vehicle for Resolving the Question Presented.

Respondents cannot dispute that the Court has had few opportunities to review the scope of the Commission's jurisdiction or that the petition implicates important trade interests. Nor can they dispute that the Federal Circuit's decision creates a large gap in the substantive protections provided to domestic industry from competitive harms caused by unfair trade practices. Because the Federal Circuit has exclusive authority over appeals from the Commission, its decision leaves a substantial portion of the nation's manufacturers unprotected from unfair trade practices merely because deceptively advertised products are also subject to regulation under the FDCA.

In a last-gasp effort to avoid review, respondents raise an insubstantial jurisdictional objection. According to respondents, because the statute contemplates judicial review of Commission determinations made after investigations are concluded, the Commission can escape judicial oversight by violating its obligation to initiate an

investigation in the first instance. Even the Federal Circuit rejected that argument. *See* App. 19. Respondents' jurisdictional argument disregards plain statutory text.

The Tariff Act grants private parties the right to "appeal" to the Federal Circuit when they are "adversely affected by a final determination of the Commission," including a determination that (1) either excludes or refuses to exclude articles from entry into the United States, or (2) either grants or refuses to grant a cease-and-desist order. 19 U.S.C. § 1337(c); *see also id.* § 1337(d), (f). Those determinations are "reviewable in accordance with section 706 of title 5." *Id.* § 1337(c).

The Commission's determination that Amarin's claims are not cognizable is thus subject to judicial review because it reflects the agency's final determination finding that "articles should not be excluded from entry," *id.* § 1337(d), and declining to issue a cease-and-desist order, *id.* § 1337(f). A "dismissal for failure to state a claim" is "a judgment on the merits." *Plaut v. Spendthrift Farm*, 514 U.S. 211, 228 (1995); *see also Amgen, Inc. v. U.S. Int'l Trade Comm'n*, 902 F.2d 1532, 1535–36 (Fed. Cir. 1990). Moreover, section 706(1) of the Administrative Procedure Act grants courts authority to compel agency action unlawfully withheld. *See Norton v. S. Utah Wilderness Alliance*, 542 U.S. 55, 63–64 (2004). That provision applies here because the Commission is under an "affirmative statutory duty" to investigate alleged unfair trade practices and its refusal to investigate "constitutes, in effect, an affirmative act that triggers 'final agency action'

review." *Sierra Club v. Thomas*, 828 F.2d 783, 793 (D.C. Cir. 1987).

There is a strong "presumption in favor of the reviewability of agency action," *Smith v. Berryhill,* 139 S. Ct. 1765, 1780 (2019), which can be rebutted "only if the relevant statute precludes review, or if the action is committed to agency discretion by law," *Weyerhaeuser Co. v. United States Fish & Wildlife Serv.*, 139 S. Ct. 361, 370 (2018) (internal citations and quotation marks omitted). The government has not met that burden. The Tariff Act's mandatory language flatly refutes any suggestion that Congress intended to commit to the Commission's unfettered discretion whether to initiate an investigation when presented with a complaint under oath. Nor has the Commission even purported to exercise any discretion it may have; instead, its decision was premised on a mistaken view of the law—its conclusion that the Tariff Act is subordinate to FDA's enforcement authority. *See SEC v. Chenery Corp.*, 318 U.S. 80, 94 (1943) ("an order may not stand if the agency has misconceived the law"). This Court has recently recognized that judicial review is appropriate when an agency engages in "shenanigans" by failing to abide by its statutory obligations. *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2142 (2016); *see also Heckler v. Chaney*, 470 U.S. 821, 833 (1985) ("Congress did not set agencies free to disregard legislative direction in the statutory scheme that the agency administers."). That principle applies with full force here.

Finally, private respondents (but not the government) argue that the Court should wait for further case development because district courts are

purportedly available to force the Commission to investigate unfair trade practices. Priv. Opp. 16–17. That is also wrong. The Federal Circuit has "exclusive jurisdiction" over the Commission's final determinations. 28 U.S.C. § 1295(a)(6). It is well settled that, "when there is a specific statutory grant of jurisdiction to the court of appeals, it should be construed in favor of review by the court of appeals." *NRDC v. Abraham*, 355 F.3d 179 (2d Cir. 2004) (citing cases). Where, as here, Congress has "channel[led] objections" through the agency and court of appeals, there is no role for the district courts. *See Scottsdale Capital v. Financial Indus. Regulatory Auth.*, 844 F.3d 414, 424 (4th Cir. 2016). Private respondents fail to cite any case where a party has been permitted to seek review of a Commission decision in district court.

* * *

Congress enacted the Tariff Act to protect domestic industries from competitive harms caused by unfair trade practices, and it required the Commission to investigate when presented with a complaint under oath. The Federal Circuit's decision below eliminates the statutory rights and obligations that Congress created based on a legal conclusion that does not take account of the Tariff Act's text, is contrary to *POM Wonderful*, and deepens a split in lower-court authority. Because the Federal Circuit has exclusive jurisdiction over Commission determinations, there is no likelihood of further development in lower court authority. There is no reason this Court should wait to grant review.

CONCLUSION

The Court should grant the petition.

Respectfully submitted,

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