No. 25A___

In the Supreme Court of the United States

JAZZ PHARMACEUTICALS, INC.,

Applicant,

v.

FOOD & DRUG ADMINISTRATION, *ET AL.*,

Respondents.

APPLICATION DIRECTED TO THE HONORABLE CHIEF JUSTICE JOHN G. ROBERTS, JR. FOR AN EXTENSION OF TIME WITHIN WHICH TO PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE D.C. CIRCUIT

CARTER G. PHILLIPS
Counsel of Record
KWAKU A. AKOWUAH
SEAN C. GRIFFIN
PETER A. BRULAND
SIDLEY AUSTIN LLP
1501 K Street NW
Washington, D.C. 20005
(202) 736-8000
cphillips@sidley.com

Counsel for Applicant Jazz Pharmaceuticals, Inc.

APPLICATION FOR EXTENSION OF TIME

To the Honorable John G. Roberts, Jr., Chief Justice of the United States and Circuit Justice for the United States Court of Appeals for the D.C. Circuit:

1. Jazz Pharmaceuticals, Inc. respectfully requests a 46-day extension, up to and including November 10, 2025, to petition for a writ of certiorari. See 28 U.S.C. § 2101(c); Sup. Ct. R. 13.5. The D.C. Circuit issued its opinion and entered judgment on June 27, 2025. The opinion is available at 141 F.4th 254, and a copy is attached. Jazz's cert petition is currently due September 25, 2025. See Sup. Ct. R. 13.3. This application has been filed on September 12, 2025, thirteen days before the time for filing the petition is set to expire. This Court has jurisdiction to review the D.C. Circuit's decision under 28 U.S.C. § 1254(1).

2. Review is warranted because the D.C. Circuit split with other circuits over an important methodological question: what evidence is needed before courts may infer that Congress implicitly incorporated an agency regulation?

a. This case involves the Orphan Drug Act of 1983, which Congress passed to spur investment in "orphan" drugs—treatments for rare disease and conditions. The statute authorizes FDA to "designate" a given drug "as a drug for a rare disease or condition." 96 Stat. 2050, *codified as amended at* 21 U.S.C. § 360bb(a)(1). Then, if FDA later approves "a drug designated … for a rare disease or condition," the statute (as originally enacted) provided that the agency "may not approve another application … for such drug for such disease or condition" for "seven years." 96 Stat. at 2051, *codified, as amended,* at 21 U.S.C. § 360cc(a). The practical effect of this approval

moratorium is that follow-on treatments are temporarily excluded from the market. This allows drugmakers to recoup their investment and serves as "the Act's chief financial incentive." *Depomed, Inc. v. HHS*, 66 F. Supp. 3d 217, 221 (D.D.C. 2014).

In 1992—during *Chevron*'s heyday—FDA promulgated regulations to implement the Act. Relevant here, FDA claimed that the statutory phrase "such drug" was ambiguous, leaving a gap for the agency to fill. To that end, FDA announced that the moratorium would not prevent it from approving any follow-on drugs that it deemed "clinically superior." 57 Fed. Reg. 62,076 (Dec. 29, 1992). FDA's regulation thus provided that a "subsequent drug" that "can be shown to be clinically superior to the first drug … will not be considered to be the same drug" as the first drug—and so will not be blocked by the moratorium. 21 C.F.R. § 316.3(b)(13)(i).

Twenty-five years later, Congress passed the FDA Reauthorization Act of 2017, which made several changes to the Orphan Drug Act. Among other amendments, Congress provided that "21 U.S.C. § 360cc[] is amended … in subsection (a) … by striking 'such drug for such disease or condition' and inserting 'the same drug for the same disease or condition' …." § 607(a)(1), 131 Stat. at 1049 (emphases added). Congress made a similar change in subsection (b), striking "such holder provides" and replacing it with "the holder provides." § 607(a)(2)(C), 131 Stat. at 1049. No legislative history explains why Congress replaced the word "such" in these provisions.

b. Jazz has spent years developing treatments for narcolepsy: a rare, chronic, and debilitating sleep condition. While narcolepsy has no known cure, a drug called oxybate has been shown to treat its symptoms. At the request of Jazz's

predecessor, FDA designated oxybate as a treatment for narcolepsy. Then, in 2020, it approved Jazz's oxybate product Xywav to treat narcolepsy. As FDA later acknowledged, the Orphan Drug Act thus barred the agency from "approv[ing] … the same drug for the same disease or condition" until 2027. 21 U.S.C. § 360cc(a).

Three years later—partway through the moratorium—FDA approved a rival oxybate treatment created by respondent Avadel CNS Pharmaceuticals, LLC. To get around the moratorium, the agency relied on the clinical-superiority loophole in its 1992 regulation. Applying that loophole here, FDA deemed Avadel's treatment "clinically superior" to Jazz's—and hence not "the same drug." That meant the moratorium didn't apply, leaving FDA free to approve Avadel's follow-on treatment.

Jazz sued FDA, arguing that the agency had violated the Orphan Drug Act. As Jazz explained, the phrase "same drug" refers back to the only other "drug" mentioned in subsection (a)—the "drug designated" by FDA as a treatment for a rare disease. Here, FDA designated the drug oxybate to treat narcolepsy, so the moratorium barred it from approving follow-on drugs (like Avadel's) that use oxybate to treat narcolepsy. And nothing in the statute authorized FDA to approve "clinically superior" drugs despite the moratorium. FDA offered two responses: *Chevron* and implicit ratification. Shortly after this Court decided *Loper Bright Enterprises* v. *Raimondo*, 603 U.S. 369 (2024), the district court rejected Jazz's challenge and accepted FDA's ratification argument. It concluded that when Congress replaced "such drug for such disease or condition" with "the same drug for the same disease or condition," it intended to "ratify and incorporate" the clinical-superiority loophole in

FDA's 1992 regulation. *Jazz Pharms., Inc.* v. *Becerra*, 2024 WL 4625731, at *13 (D.D.C. Oct. 30, 2024).

The D.C. Circuit affirmed. The court recognized that "Congress did not expressly incorporate [FDA's policy] by cross-referencing in the statute the regulatory provision, as it has done" elsewhere. *Jazz Pharms., Inc.* v. *Kennedy*, 141 F.4th 254, 262 (D.C. Cir. 2025). Still, the panel thought that evidence of ratification "abound[ed]." *Id.* First, it observed that FDA had promulgated its regulation twenty-five years before the 2017 amendments. Second, it deemed "same drug" an "unusual term." And finally, it ventured that other changes that Congress made in 2017 showed that Congress "had in mind the FDA's regulations" and "was thinking about regulatory implementation." *Id.* at 263–65.

c. Other circuits do not infer ratification so easily. In the Eleventh Circuit, long regulatory history and linguistic overlap are not enough to infer ratification. In *CSX Corp.* v. *United States*, 18 F.4th 672, 681 (11th Cir. 2021) (Pryor, C.J.), the agency argued that "Congress essentially adopted the meaning of" a regulation that had been on the books for thirty-two years. *Id.* at 679, 681. Despite the age of the regulation and its substantial overlap with the statute, the Eleventh Circuit reasoned that it was not "obvious" that the statute was "transplanted from" the regulation. *Id.* at 681. Likewise, the Federal Circuit deems it "of little import that Congress was aware of [an agency's] previous definition." *Veterans Justice Grp., LLC* v. *Sec'y of Veterans Affairs*, 818 F.3d 1336, 1349 (Fed. Cir. 2016). "The relevant inquiry is not whether Congress was aware of the prior regulations, but whether it intended to bind

the [agency] to its existing definition via the enactment" of a given statute. *Id.* And the Sixth Circuit holds that courts "must exercise extreme care in determining that Congress has authoritatively agreed with an agency's interpretation of a statute"—especially when "the agency's interpretation" is "textually implausible." *Tiger Lily, LLC* v. *HUD*, 5 F.4th 666, 673 (2021).

d. The proper bounds of ratification is an important and recurring question. Two Terms ago, this Court held that courts "may not defer to an agency interpretation of the law simply because a statute is ambiguous." *Loper Bright*, 603 U.S. at 413. Yet the decision below gives agencies a roadmap for reaching the same outcome whenever Congress legislates in an area where the agency has already expressed views. Step one: find a longstanding regulation that overlaps with the words of a later-enacted statute. (Not a tall order when Congress and the agency are talking about the same issues.) Step two: attribute knowledge of that regulation to Congress. Step three: argue that courts must interpret the statute the same way that the agency interprets its own regulation. *Cf. Kisor* v. *Wilkie*, 588 U.S. 558, 580 (2019) ("*Auer* deference gives an agency significant leeway to say what its own rules mean."). Now that *Chevron* is gone, this issue is taking on greater salience—and creating uncertainty among the lower courts. See, *e.g.*, *Duffis* v. *MaineHealth*, 2025 WL 1928339, at *18 (D. Maine July 14, 2025) ("[I]t is not clear whether the legislative ratification canon applies to administrative interpretations after *Loper Bright*.").

3. There is good cause for a 46-day extension. Since the D.C. Circuit's decision came down, counsel have also been addressing, and must continue to

address, numerous deadlines stretching from July to October, including briefing in several cases before this Court. These deadlines have made and will continue to make it difficult to seek this Court's review by September 25, 2025. Counsel's competing deadlines and argument dates include and have included:

- July 9, 2025: supplemental brief filed in *Pritchard* v. *Blue Cross Blue Shield of Illinois*, No. 23-4331 (9th Cir.);
- July 15, 2025: oral argument in *Clemmons* v. *Randy Lehr*, Nos. 1426-EDA-2024 & 1475-EDA-2024 (Pa. Super. Ct.);
- July 21, 2025: amicus brief in support of defendant-appellant filed in *Penelow* v. *Janssen Products, L.P.*, No. 25-1818 (3d Cir.);
- July 30, 2025: opposition to proposed judgment filed in *State of Oklahoma* v. *Tyson Foods, Inc.*, No. 05-cv-329 (N.D. Okla.);
- July 31, 2025: oral argument in *Merck & Co. Inc.* v. *Merck KGaA*, No. 2:16-cv-00266 (D.N.J.);
- August 13, 2025: reply brief filed in *Banco San Juan Internacional* v. *The Federal Reserve Bank of NY*, No. 25-1144 (2d Cir.);
- August 14, 2025: *Daubert* motions filed in *Furdek* v. *Amazon.com, Inc.*, No. 22-cv-1599 (W.D. Wash.);
- August 14, 2025: opposition to class certification filed in *Furdek* v. *Amazon.com, Inc.*, No. 22-cv-1599 (W.D. Wash.);
- August 15, 2025: reply brief and response brief filed in *Lang* v. *Sig Sauer*, Nos. 25-10810 & 25-10812 (11th Cir.);
- August 18, 2025: amicus brief in support of petition for certiorari filed in *Murphy* v. *United States*, 25-61 (U.S.);
- August 25, 2025: briefs in response to motion to dismiss filed in *American Free Enterprise Chamber of Commerce* v. *EPA*, No. 25-98 (and consolidated cases) (D.C. Cir.) and *American Free Enterprise Chamber of Commerce* v. *EPA*, No. 25-106 (and consolidated cases) (D.C. Cir.);
- August 28, 2025: amicus brief in support of plaintiff-appellant filed in *Vertex* v. *HHS*, 25-5133 (D.C. Cir.);

- September 2, 2025: reply in support of petition for certiorari filed *Kingdom of Spain* v. *Blasket Renewable Investments, LLC*, No. 24-1130 (U.S.);
- September 10, 2025: amicus brief supporting petitioner due in *Galette* v. *New Jersey Transit*, No. 24-1021 (U.S.);
- Sept. 12, 2025: rehearing petition for defendant-appellee due in *San Diego County Retirement Association* v. *Johnson & Johnson*, No. 24-1409 (3d Cir.);
- Oct. 9, 2025: supplemental brief due in *Devas Multimedia Private Ltd.* v. *Antrix Corp. Ltd.*, Nos. 20-36024, 22-35085, 22-35103 (9th Cir.).

Given this press of existing business, an extension is necessary to ensure that counsel have adequate time to craft a petition that will best assist this Court in determining whether to grant review.

CONCLUSION

The Court should extend the deadline for Jazz's petition by 46 days, up to and including November 10, 2025.

September 12, 2025

Respectfully submitted,

/s/ Carter G. Phillips

CARTER G. PHILLIPS
Counsel of Record
KWAKU A. AKOWUAH
SEAN C. GRIFFIN
PETER A. BRULAND
SIDLEY AUSTIN LLP
1501 K Street NW
Washington, D.C. 20005
(202) 736-8000
cphillips@sidley.com

Counsel for Applicant Jazz Pharmaceuticals, Inc.