United States Court of Appeals for the Fifth Circuit

United States Court of Appeals
Fifth Circuit
FILED
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Lyle W. Cayce
Clerk

No. 25-10600

OUTSOURCING FACILITIES ASSOCIATION; NORTH AMERICAN CUSTOM LABORATORIES, L.L.C. PARTNERS, *doing business as* FARMAKEIO CUSTOM COMPOUNDING,

Plaintiffs—Appellants,

versus

FOOD & DRUG ADMINISTRATION; KYLE DIAMANTAS, *Acting Commissioner, U.S. Food and Drug Administration*,

Defendants—Appellees,

versus

ELI LILLY AND COMPANY,

Intervenor—Appellee.

Appeal from the United States District Court
for the Northern District of Texas
USDC No. 4:24-CV-953

Before RICHMAN, DUNCAN, and OLDHAM, *Circuit Judges*.

PER CURIAM:[*]

This case presents issues similar to those in *Outsourcing Facilities Association v. FDA v. Novo Nordisk Incorporated*, which is also before our panel. Both cases concern GLP-1 drugs approved by the Food and Drug Administration (FDA) that are designed to treat type-2 diabetes and obesity and the FDA's decisions to remove the drugs from its drug shortage list. The appeals have not been consolidated, and we are issuing separate opinions.

We consider here the FDA's decision regarding Mounjaro and Zepbound, drugs manufactured by Eli Lilly & Company (Eli Lilly), that contain tirzepatide as their active ingredient. The FDA removed these tirzepatide-injection products from its drug shortage list in October 2024, which made it unlawful for physicians, pharmacies, and outsourcing facilities to compound tirzepatide-injection products. Appellants, representing various compounders, assert that the FDA's decision violated the Administrative Procedure Act (APA) because: (1) the FDA should have proceeded under the APA's notice-and-comment rulemaking procedures, and (2) the FDA's shortage determination was arbitrary and capricious. The district court concluded that the FDA did not violate the APA in either respect. We affirm.

I

The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, (FD&CA) generally requires the FDA to approve new drugs sold in the United States.[1] Garnering FDA approval is a "long, comprehensive, and

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[*] This opinion is not designated for publication. *See* 5TH CIR. R. 47.5.

[1] *See* 21 U.S.C. § 355(a).

costly testing process."[2] Eli Lilly received FDA approval for its name-brand prescription drug products, Mounjaro and Zepbound, in May 2022 and November 2023 respectively. At that time, the FDA approved both drugs as "pre-filled single-dose pens."

The active ingredient in both Mounjaro and Zepbound, tirzepatide, is a glucagon-like peptide-1 (GLP-1) receptor agonist that helps manage blood sugar levels. Mounjaro treats type-2 diabetes and Zepbound treats obesity and other weight-related conditions. Eli Lilly manufactures each drug in a variety of dosage strengths, and patients usually start at the lowest dosage strength and titrate up to higher dosage strengths over time as needed. Mounjaro and Zepbound are the only FDA-approved tirzepatide products. By virtue of 21 U.S.C. § 355(c)(3)(E)(ii), the FDA is prohibited from approving applications from any other manufacturer for a drug using the same "active moiety" (essentially the same active ingredient), which is tirzepatide here, for five years after the FDA initially approves the medications.[3] Eli Lilly's right to exclusively manufacture tirzepatide products extends to 2027.

In addition to the FD&CA creating a period of limited exclusivity, it also prohibits physicians, pharmacies and outsourcing facilities from compounding drugs that are either "essentially copies of a commercially available drug product"[4] or "essentially a copy of one or more approved drugs."[5] Compounded drugs are the result of "a process by which a

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[2] *FTC v. Actavis, Inc.*, 570 U.S. 136, 142 (2013) (citing 21 U.S.C. § 355(b)(1)).

[3] *See* 21 U.S.C. §§ 355(c)(3)(E)(ii), (j)(5)(F)(ii); *see also* 21 C.F.R. § 314.3 (defining active moiety).

[4] 21 U.S.C. § 353a(b)(1)(D).

[5] 21 U.S.C. § 353b(a)(5).

pharmacist or doctor combines, mixes, or alters ingredients to create a medication."[6] Compounded drugs do not undergo the "long, comprehensive, and costly testing process"[7] that FDA-approved drugs do, but they still must meet certain statutory conditions.[8]

The FD&CA's compounding prohibition is temporarily suspended when the drug product appears on the FDA's drug shortage list.[9] The FD&CA requires the FDA to "maintain an up-to-date list of drugs that are determined by [the FDA] to be in shortage in the United States,"[10] and it defines a "drug shortage" as the "period of time when the demand or projected demand for the drug within the United States exceeds the supply of the drug."[11]

The FDA added Mounjaro to its drug shortage list in December 2022 and Zepbound in April 2024. Pharmacies and outsourcing facilities that met the statutory conditions were accordingly able to compound drugs to satisfy

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[6] *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 361-62 (2002).

[7] *See* FDA, *Human Drug Compounding Laws* (2024), https://www.fda.gov/drugs/human-drug-compounding/human-drug-compounding-laws (Dec. 17, 2024) ("Compounded drugs are not FDA-approved. This means that FDA does not review these drugs to evaluate their safety, effectiveness, or quality before they reach patients.").

[8] *See* 21 U.S.C. §§ 353a, 353b; FDA, Compounding when Drugs are on FDA's Drug Shortages List (2025), https://www.fda.gov/drugs/human-drug-compounding/compounding-when-drugs-are-fdas-drug-shortages-list ("Generally, when an FDA approved drug is on FDA's drug shortages list some federal law restrictions may not apply, such as restrictions on compounding drugs that are essentially copies of approved drugs. . . . [C]ompounders may be able to make a compounded version of that drug if they meet certain federal law conditions and recruitments.").

[9] *See* 21 U.S.C. §§ 353a(b)(1)(D), 353b(a)(2)(A)(ii), (a)(5), (d)(2)(A).

[10] *Id.* § 356e(a).

[11] *Id.* § 356c(h)(2).

the demand for individuals who required medication containing tirzepatide. The FDA did not engage in notice-and-comment rulemaking before adding Mounjaro and Zepbound to its drug shortage list.

While Mounjaro and Zepbound were on the FDA's drug shortage list, Eli Lilly spent approximately $23 billion to increase its manufacturing capacity by building, expanding, acquiring, and obtaining internal and external manufacturing facilities in the United States and Europe. Eli Lilly also garnered FDA approval to sell single-dose vials of Mounjaro and Zepbound in addition to the single-dose injection-pens already approved.

On October 2, 2024, the FDA posted a public update on its website "determin[ing] the shortage of tirzepatide injection . . . medication . . . resolved."[12] Outsourcing Facilities Association and North American Custom Laboratories, LLC, doing business as FarmaKeio Custom Compounding (the Compounders), filed a lawsuit against the FDA shortly after. The district court granted the FDA's unopposed motion for a voluntary remand and stay to reevaluate its October decision. Three months later the FDA confirmed on December 19, 2024 that the shortage was resolved. The FDA concluded that Eli Lilly's supply would "meet or exceed projected demand" in light of Eli Lilly's expanded manufacturing capacity and the information and data Eli Lilly, patients, healthcare providers, compounders, and others had provided.

The FDA issued a "Declaratory Order" and "Decision Memorandum" to memorialize its December 2024 decision (the Delisting Action) and stated its "order [wa]s the product of an informal adjudication

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[12] *See* FDA, *FDA Clarifies Policies for Compounders as National GLP-1 Supply Begins to Stabilize* (Oct. 2, 2024), https://www.fda.gov/drugs/drug-alerts-and-statements/fda-clarifies-policies-compounders-national-glp-1-supply-begins-stabilize.

in which FDA evaluated the information available to [it] to make a determination of the relevant facts regarding the affected drug products, and applied the statutory standard for drug shortages to those facts." The FDA invoked its adjudicatory power under 5 U.S.C. § 554(e)—the section of the APA entitled "Adjudications"—and explained it was issuing the order to "remove uncertainty as to the status of the shortages of tirzepatide injection drug products." It also "note[d] that th[e] order . . . included notice to affected parties via publication of the shortage determination on the FDA's website, and an opportunity for affected parties to be heard by submitting information to [the FDA] for consideration." The FDA then observed that "[m]ultiple interested parties, including [Eli Lilly], individual patients, pharmacy compounders, outsourcing facilities, associations representing pharmacy compounders and outsourcing facilities, . . . and telehealth companies, did in fact submit information," both before the initial October 2024 shortage determination and during the reevaluation of that decision. Additionally, the FDA stated that it would not take action against compounders for "violations of the [FD&CA] arising from conditions that depend on tirzepatide injection products" for a period of sixty or ninety days depending on the type of compounder "to avoid unnecessary disruption to patient treatment and to help facilitate an orderly transition."

The district court granted the Compounders' motion to reopen the suit and Eli Lilly's motion to intervene. The Compounders moved for a preliminary injunction seeking to prevent the FDA from taking action against them for compounding tirzepatide-injection products. They argued that the FDA "unlawfully promulgated the Delisting Action" by failing to engage in notice-and-comment rulemaking and that the Delisting Action was arbitrary and capricious. The district court denied the Compounders' motion, reasoning that they were unlikely to succeed on the merits. Recognizing that "the regulatory scheme is seemingly silent as to what procedure the FDA

must use to make its shortage determination" for either addition or removal of a drug, the district court concluded that the "FDA did not abuse its discretion by choosing to proceed through adjudication." It also concluded that the "FDA's treatment of the evidence submitted" by the Compounders and others "was reasonable."

The Compounders appealed the district court's denial of their preliminary-injunction motion and a panel of this court held that the Compounders "ha[d] not made their 'clear showing'" that the Compounders were likely to succeed on the merits for "the reasons given by the district court in its thorough opinion explaining its denial." The parties then filed cross motions for summary judgment based on the full administrative record. The district court entered summary judgment in favor of the FDA and Eli Lilly, rejecting the Compounders' notice-and-comment rulemaking and arbitrary and capricious arguments for a second time. The district court entered final judgment, and the Compounders timely appealed.

II

Assuming, without deciding, that the FDA erred by not subjecting its decision to the APA's notice and comment procedures, we conclude that the Compounders have not met their burden to show prejudice. We also conclude that the FDA's shortage determination was not arbitrary or capricious.

A

"This court reviews the district court's grant of summary judgment *de novo*."[13] Whether agency action is "a 'rule' for APA purposes is purely a matter of construction of the APA" that we also "review[] . . . de novo."[14]

The Compounders assert the Delisting Action is a substantive rule subject to the APA's notice-and-comment mandate because: (1) "[t]he Delisting Action is a statement of general applicability to all compounders that prescribes law by prohibiting most tirzepatide compounding"; (2) "[t]he Delisting Action . . . has the force and effect of law" because it affects individual rights and obligations; (3) agencies' listing decisions have "consistently been recognized as substantive rules subject to notice and comment"; and (4) nothing in the FD&CA "displaces the APA's notice-and-comment procedures."

The FDA contends that the "ultimate product" of its Delisting Action "bears all of the relevant characteristics of an adjudication" because it did not announce a new interpretation of the FD&CA or establish a new standard or policy and its decision has an immediate and determinable impact on specific factual scenarios. The FDA reasons that it applied Congress's straightforward definition of a drug shortage under 21 U.S.C. § 356c(h)(2)—whether demand exceeds supply—to a particular set of facts—whether demand for tirzepatide products exceeds Eli Lilly's supply—and decided that Eli Lilly's supply "was bigger than" demand for tirzepatide products. The FDA also cites various cases in which this court has

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[13] *Shell Offshore Inc. v. Babbitt*, 238 F.3d 622, 627 (5th Cir. 2001) (citing *Hernandez v. Reno*, 91 F.3d 776, 779 (5th Cir. 1996)).

[14] *Id.* (citing *Phillips Petrol. Co. v. Johnson*, 22 F.3d 616, 619 (5th Cir. 1994)).

categorized an agency's declaratory ruling as an informal adjudication[15] when made pursuant to its adjudicatory power under 5 U.S.C. § 554(e), which gives agencies authority to "issue a declaratory order to terminate a controversy or remove uncertainty."[16] The FDA emphasizes that its declaratory order here explained its purpose as "remov[ing] uncertainty as to the status of the relevant tirzepatide injection products," tracking the language in § 554(e).

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Under the APA, a "'rule' is 'an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy.'"[17] "The APA obligates agencies to subject their substantive rules to notice and comment."[18] "Adjudicative orders, on the other hand, are not rules at all and therefore need not go through notice and comment."[19] "[T]he APA . . . defines 'adjudication' as the process for formulating an 'order'" and an "'order' [as the] 'final disposition . . . of an agency in a matter other than rulemaking.'"[20] An adjudication is, therefore,

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[15] *City of Arlington v. FCC*, 668 F.3d 229, 241 (5th Cir. 2012), *aff'd*, 569 U.S. 290 (2013) ("Because § 554(e) is a subsection of the provision in the APA governing formal adjudication, we have held that declaratory rulings issued pursuant to its grant of authority are informal adjudications under the APA.") (collecting cases).

[16] 5 U.S.C. § 554(e).

[17] *W & T Offshore, Inc. v. Bernhardt*, 946 F.3d 227, 237 (5th Cir. 2019) (citing 5 U.S.C. § 551(4)).

[18] *Id.*; *see* 5 U.S.C. § 553.

[19] *W & T Offshore, Inc.*, 946 F.3d at 237.

[20] *Sierra Club v. Peterson*, 185 F.3d 349, 366 (5th Cir. 1999) (last alteration in original) (quoting 5 U.S.C. § 551(6)).

"any agency process that results in a final disposition, except for rulemaking."[21]

This court "examine[s] two aspects of an agency action when determining whether an agency action was a rulemaking or an adjudication."[22] "First, we consider the agency's characterization of its own action."[23] "Second, we . . . examine the ultimate product of the agency action."[24] Agencies "enjoy 'very broad discretion [in deciding] whether to proceed by way of adjudication or rulemaking'"[25] "in the absence of a clear congressional directive spelling out a particular method."

As the FDA points out, our decisions in *City of Arlington v. FCC*,[26] *American Airlines Inc. v. Department of Transportation*,[27] and *Texas v. United States*[28] are relevant here. In *City of Arlington*, this court concluded that a Department of Transportation (DOT) ruling "designated as a 'Declaratory Ruling'" and issued pursuant to its powers under § 554(e) was "the product of adjudication."[29] Essentially, DOT invoking its § 554(e) power and labeling its order "declaratory" was enough for us to conclude DOT's action

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[21] *Id.*

[22] *City of Arlington v. FCC*, 668 F.3d 229, 240 (5th Cir. 2012), *aff'd*, 569 U.S. 290 (2013).

[23] *Id.* (citing *Am. Airlines, Inc. v. Dep't of Transp.*, 202 F.3d 788, 797 (5th Cir. 2000)).

[24] *Id.* (citing *Am. Airlines, Inc.*, 202 F.3d at 797).

[25] *Id.* (alteration in original) (quoting *Time Warner Ent. Co. v. FCC*, 240 F.3d 1126, 1141 (D.C. Cir. 2001)).

[26] 668 F.3d 229 (5th Cir. 2012), *aff'd*, 569 U.S. 290 (2013).

[27] 202 F.3d 788 (5th Cir. 2000).

[28] 866 F.2d 1546 (5th Cir. 1989).

[29] *City of Arlington*, 668 F.3d at 241.

was "the product of adjudication."[30] We explained this court has "held that declaratory rulings issued pursuant to [§ 554(e)] are informal adjudications under the APA" because "§ 554(e) is a subsection of the provision in the APA governing formal adjudication."[31] But we made clear that an agency must not "be able to escape the APA's notice-and-comment requirements simply by labeling a rulemaking an adjudication."[32] "Although . . . agencies enjoy broad discretion in choosing whether to establish a rule through adjudication or rulemaking, that discretion is not unlimited."[33] "The agency ultimately remains subject to the constraints of the APA, which requires courts to review the agency's" decision to proceed "through adjudication or rulemaking" and determine whether it was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law."[34]

In *American Airlines* we concluded that DOT "engaged in adjudication rather than rulemaking" "[s]ince the APA defines 'adjudication' as the 'agency process for formulating an order' and DOT classifie[d] its ruling as a declaratory order."[35] Again, DOT invoking its § 554(e) power and labeling its order "declaratory" was enough for us to conclude that DOT's action was an adjudication. Like in *City of Arlington*,

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[30] *Id.*

[31] *Id.*

[32] *Id.*

[33] *Id.* (citation omitted) (citing *Am. Airlines, Inc. v. Dep't of Transp.*, 202 F.3d 788, 797 (5th Cir. 2000)).

[34] *Id.* (quoting 5 U.S.C. § 706(2)(A)).

[35] *Am. Airlines, Inc.*, 202 F.3d at 797-98.

this court then reviewed for an abuse of discretion DOT's decision to proceed by adjudication instead of rulemaking.[36]

We proceeded similarly in *Texas v. United States*.[37] There, the ICC issued a declaratory order "pursuant to the authority conferred by 5 U.S.C. § 554(e) . . . 'to terminate a controversy or remove uncertainty.'"[38] This court stated that "such [§ 554(e)] adjudications are subject to judicial review only to determine whether they are 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance of law.'"[39]

Here, the FDA maintains that it issued its declaratory order pursuant to its § 554(e) adjudicatory authority to "terminate a controversy or remove uncertainty."[40] We need not decide whether the FDA abused its discretion in so proceeding,[41] because "any failure by [the FDA] to comply with the APA in this case was harmless."[42]

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"An agency's failure to comply with the APA is harmless when the agency's mistake 'clearly had no bearing on the procedure used or the

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[36] *Id.* at 798.

[37] 866 F.2d 1546, 1555-56 (5th Cir. 1989).

[38] *Id.* at 1555 (quoting 5 U.S.C. § 554(e)).

[39] *Id.* at 1555-56 (quoting 5 U.S.C. § 706(2)(A)).

[40] *See* 5 U.S.C. § 554(e).

[41] *City of Arlington v. FCC*, 668 F.3d 229, 241-42 (5th Cir. 2012) (recognizing that in "certain situations . . . an agency's reliance on adjudication instead of rulemaking constitutes an abuse of discretion"), *aff'd*, 569 U.S. 290 (2013).

[42] *Id.* at 243 (citing *United States v. Johnson*, 632 F.3d 912, 930 (5th Cir. 2011)).

substance of decision reached.'"[43] In conducting the harmless error inquiry, we consider several factors including:

> (1) "an estimation of the likelihood that the result would have been different"; (2) "an awareness of what body (jury, lower court, administrative agency) has the authority to reach that result"; (3) "a consideration of the error's likely effects on the perceived fairness, integrity, or public reputation of judicial proceedings"; and (4) "a hesitancy to generalize too broadly about particular kinds of errors when the specific factual circumstances in which the error arises may well make all the difference."[44]

Because the Compounders argue the FDA violated the APA by failing to comply with its notice and comment procedures, the "touchstone" of our inquiry is "whether it is clear that the lack of notice and comment did not prejudice" the Compounders.[45] The burden is on the Compounders to show prejudice,[46] and they do not make that showing here.

"[T]he APA requires agencies to publish a notice of proposed rulemaking in the Federal Register before promulgating a rule that has legal force" absent a statutory exception[47] or persons subject to the rule "hav[ing] actual notice."[48] "Aside from [its] notice requirements, the APA mandates

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[43] *Id.* at 244 (quoting *U.S. Steel Corp. v. EPA*, 595 F.2d 207, 215 (5th Cir. 1979)).

[44] *Id.* (quoting *Shinseki v. Sanders,* 556 U.S. 396, 411-12 (2009)).

[45] *Id.* (quoting *United States v. Johnson*, 632 F.3d 912, 931 (5th Cir. 2011)).

[46] *See id.* at 243 ("[T]he harmless error rule requires the party asserting error to demonstrate prejudice from the error." (alteration in original) (quoting *Air Can. v. Dep't of Transp.,* 148 F.3d 1142, 1156 (D.C. Cir. 1998))).

[47] *Little Sisters of the Poor Saints Peter and Paul Home v. Pennsylvania*, 591 U.S. 657, 683 (2020).

[48] 5 U.S.C. § 553(b).

that agencies [(1)] 'give interested persons an opportunity to participate'" by submitting views, (2) concisely state its reasoning in its final rule, and (3) publish the rule "30 days before [it] become[s] effective."[49] "[T]he APA generally requires only a minimum thirty-day comment period," and "while interested parties should be able to participate meaningfully in the rulemaking process, the public need not have an opportunity to comment on every bit of information influencing an agency's decision."[50] Overall, "[t]he object [of notice and comment] . . . is one of fair notice."[51]

Here, the FDA did not publish a notice in the Federal Register. But the Compounders—the "persons subject" to the FDA's action—"ha[d] actual notice."[52] The Compounders admit that they "were aware of FDA's consideration" of whether tirzepatide injection-products were still in shortage. They argue that other interested parties, such as patients, providers, and insurers, did not have notice, and "[t]hat matters" because the more evidence, the more weight it "carr[ies.]"

The administrative record contradicts the Compounders' argument.[53] The FDA posted public updates on its website about the status of tirzepatide products under a page titled "FDA clarifies policies for compounders as

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[49] *Little Sisters*, 591 U.S. at 685-86 (citing 5 U.S.C. §§ 553(b)-(d)).

[50] *Chamber of Com. of U.S. v. SEC*, 85 F.4th 760, 779 (5th Cir. 2023) (internal quotation marks omitted) (quoting *Tex. Off. of Pub. Util. Couns. v. FCC*, 265 F.3d 313, 326 (5th Cir. 2001)).

[51] *Little Sisters*, 591 U.S. at 684 (second alteration in original) (quoting *Long Island Care at Home, Ltd. v. Coke*, 551 U.S. 158, 174 (2007)).

[52] 5 U.S.C. § 553(b).

[53] FDA, *FDA Clarifies Policies for Compounders as National GLP-1 Supply Begins to Stabilize* (Apr. 1, 2026), https://www.fda.gov/drugs/drug-alerts-and-statements/fda-clarifies-policies-compounders-national-glp-1-supply-begins-stabilize

national GLP-1 supply begins to stabilize."[54] As early as September 9, 2024—almost a month prior to FDA's initial October 2 shortage determination—attorneys who represent various compounders reached out to the FDA with tirzepatide shortage data. When the FDA voluntarily moved in the district court to remand and stay the case in response to the Compounders filing suit in October 2024, in its motion, the FDA identified its legal authority to delist tirzepatide products and explained that the Compounders "may submit additional information regarding tirzepatide's availability." On October 22, FDA posted an update on its website that it would be reevaluating its initial October 2 determination, apprising interested parties not involved in the lawsuit between the FDA and the Compounders.[55]

There were almost sixty days between the FDA's October 22 posting and the FDA's December 19 Delisting Action, essentially doubling the thirty-day-minimum comment period this court has said the APA requires.[56] The Compounders, patients, pharmacies, providers, and many others submitted numerous comments and other information to the FDA during this time period,[57] and the FDA considered and addressed these submissions in its

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[54] FDA, *FDA Clarifies Policies for Compounders as National GLP-1 Supply Begins to Stabilize* (Apr. 1, 2026), https://www.fda.gov/drugs/drug-alerts-and-statements/fda-clarifies-policies-compounders-national-glp-1-supply-begins-stabilize.

[55] FDA, *FDA Clarifies Policies for Compounders as National GLP-1 Supply Begins to Stabilize* (Oct. 22, 2024), https://www.fda.gov/drugs/drug-alerts-and-statements/fda-clarifies-policies-compounders-national-glp-1-supply-begins-stabilize.

[56] *See Chamber of Com. of U.S. v. SEC*, 85 F.4th 760, 779 (5th Cir. 2023) (internal quotation marks omitted) (quoting *Tex. Off. of Pub. Util. Couns. v. FCC*, 265 F.3d 313, 326 (5th Cir. 2001)).

[57] *Cf. City of Arlington v. FCC*, 668 F.3d 229, 244-45 (5th Cir. 2012) (noting that the FCC "received and considered comments from dozens of interested parties, including several of the [parties] involved in this litigation"), *aff'd*, 569 U.S. 290 (2013).

Delisting Action. Even if, as the Compounders argue, *other* interested parties did not have actual notice or an opportunity to meaningfully participate, the Compounders do not identify how *other* interested parties' lack of involvement prejudiced them.

The Compounders seem to suggest that the FDA's allegedly holding the evidence it received from the Compounders and other interested parties to "idiosyncratic standards" prejudiced them because if there was "adequate notice," there would have been more evidence, and the FDA would not have subjected the evidence to such "idiosyncratic standards." But that is not a lack of notice argument; it just takes issue with how the FDA weighed the evidence before it. The FDA dismissed evidence suggesting a shortage persisted due to its lack of probative value, as discussed below. Regardless, the Compounders do not identify any additional information that would have been submitted to the FDA had it published a formal notice in the Federal Register or extended the period during which it considered the information before it.[58]

The Compounders have not met their burden to demonstrate prejudice. Any error in the FDA's decision to forego notice and comment procedures in removing tirzepatide products from the drug shortage list was harmless.

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[58] *See City of Arlington*, 668 F.3d at 245 (recognizing that the "goals" of public notice "may be achieved in cases where the agency's decision-making process centered on the identical substantive claims as those proposed by the party asserting error, even if there were APA deficiencies" and that "when a party's claims were considered, even if notice was inadequate, the challenging party may not have been prejudiced." (quoting *United States v. Johnson*, 632 F.3d 912, 931 (5th Cir. 2011))).

B

The Compounders argue that the FDA's decision was arbitrary and capricious because (1) it did not choose a "period of time" for its analysis, (2) it should not have relied on Eli Lilly's data presented in "arbitrary" and "incompatible" formats, (3) the FDA's findings were contradicted by the evidence, and (4) the FDA improperly dismissed evidence of a shortage.

Under the APA, we evaluate a final agency action to determine if it was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law."[59] "Agency decisions are 'presumptively valid'"[60] and "[t]he scope of review under the 'arbitrary and capricious' standard is narrow."[61] We are "not to substitute [our] judgment for that of the agency."[62]

"[A]n agency must 'disclose the basis' of its action" to permit meaningful judicial review.[63] Courts, in turn, must not "weigh the evidence pro and con but"[64] "must 'consider whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment.'"[65] The Supreme Court has "frequently reiterated that an

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[59] 5 U.S.C. § 706(2)(A).

[60] *Barr v. SEC*, 114 F.4th 441, 447 (5th Cir. 2024) (quoting *Tex. Tech Physicians Assocs. v. U.S. Dep't of Health & Hum. Servs.*, 917 F.3d 837, 844 (5th Cir. 2019)).

[61] *Motor Vehicle Mfrs. Ass'n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 30 (1983).

[62] *Id.*

[63] *Dep't of Com. v. New York*, 588 U.S. 752, 780 (2019) (quoting *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 167-169 (1962)).

[64] *Delta Found., Inc v. United States*, 303 F.3d 551, 563 (5th Cir. 2002).

[65] *State Farm Ins. Co.*, 463 U.S. at 43 (quoting *Bowman Transp., Inc. v. Arkansas-Best Freight Sys., Inc.,* 419 U.S. 281, 285 (1974)).

agency must cogently explain why it has exercised its discretion in a given manner."[66] Ultimately, though, we "focus[] on whether an agency articulated a rational connection between the facts found and the decision made."[67] "Illogic and internal inconsistency are characteristic[s] of arbitrary and unreasonable agency action."[68]

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The Compounders argue the FDA did not "disclose what 'period of time' [it] chose to analyze" or "justify such a choice." They contend the FDA relied on Eli Lilly's "choosing the time period" through its submission of data derived from its "internal (confidential) accounting," and that the data it did consider "disrespects Congress's directive to make shortage determinations based on recent information" since it gave "equal weight to data that was more than six months old."

The FDA disclosed what period of time it chose to analyze. Every table and figure containing information it considered included year-to-date data between January 2024 and November 2024, and projected data through March 2025. The FDA's justification for considering data from the eleven months leading up to its Delisting Action, and projected data for the four months after its Delisting Action, does not conflict with the FD&CA's requirements. The FD&CA requires the FDA to maintain an "up-to-date"[69] list of drugs in shortage, with shortage being defined as "a period of time when the demand or projected demand for the drug within the United States

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[66] *Id.* at 48.

[67] *Mexican Gulf Fishing Co. v. U.S. Dep't of Com.*, 60 F.4th 956, 971 (2023) (quoting *ExxonMobil Pipeline Co. v. U.S. Dep't of Transp.*, 867 F.3d 564, 571 (5th Cir. 2017)).

[68] *Chamber of Com. of U.S. v. U.S. Dep't of Lab.*, 885 F.3d 360, 382 (5th Cir. 2018).

[69] 21 U.S.C. § 356e(a).

exceeds the supply of the drug."[70] The data the FDA considered from January 2024 to March 2025 was "up-to-date," consistent with the statutory mandate. "The administrative record . . . need only 'indicate the determinative reason for the final action taken,' and [this court] may 'uphold a decision of less than ideal clarity if the agency's path may reasonably be discerned.'"[71] It is reasonably discernable here.

That the FDA considered data over a fifteen-month period does not make its decision unreasonable, as it considered data both immediately prior to, and for the projected months following, its Delisting Action. Considering data across this period of time provided a more comprehensive understanding of supply and demand, and it was consistent with the statutory mandate to make "up-to-date" shortage determinations to consider both six-month-old data and data for the months immediately prior to and following the Delisting Action.[72] Moreover, mere consideration of six-month old data does not mean the FDA gave it "equal weight," and there is no indication it did so in its Delisting Action.

2

The Compounders take issue with the FDA's reliance on Eli Lilly's data, arguing it was presented in "arbitrary and incompatible temporal formats." They first point to Table 1, which they state presents "snapshots" of data taken from "random days" and argue that a surplus on one day cannot establish a surplus on other days. They contend that is "why an accounting

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[70] *Id.* § 356c(h)(2).

[71] *Pension Benefit Guar. Corp. v. Wilson N. Jones Mem'l Hosp.*, 374 F.3d 362, 367 (5th Cir. 2004) (citation omitted) (first quoting *Camp v. Pitts*, 411 U.S. 138, 143 (1973); and then quoting *Bowman Transp., Inc. v. Arkansas–Best Freight Sys., Inc.*, 419 U.S. 281, 286 (1974)).

[72] 21 U.S.C. § 356e(a); *see also id.* § 356c(h)(2).

of inventory for a monthly period should contain at a minimum" "beginning inventory," "purchases during the month," and "ending inventory," which Eli Lilly's data did not provide.

The FDA did not act unreasonably in considering the data contained in Table 1. Table 1 provides biweekly net inventory balance (net supply available after accounting for demand) at Eli Lilly for finished and semi-finished product. The FDA considered Eli Lilly's net inventory balance from Table 1 alongside Eli Lilly's overall monthly supply.

The Compounders also point out that Eli Lilly offered its data in a "cumulative" format, which they argue "ma[d]e it impossible to know if supply me[t] demand as of the latter months" because Eli Lilly "added into each month's figures the figures from all prior months." They also contend that using January 2024 as the starting point "leaves it a mystery how the analysis would be different from a different starting point."

The FDA's decision to analyze cumulative data was not unreasonable. Focusing on individual months would have resulted in analyzing inaccurate information. A surplus of tirzepatide products from one month can partially satisfy demand for the next month since tirzepatide products may be stored for up to 24 months. The FDA's failure to explicitly state this rationalization is not a reason to set aside the Delisting Action. It is obvious that surplus may be carried over into the next month,[73] and in fact, the data demonstrates as

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[73] *Wilson N. Jones Mem'l Hosp.*, 374 F.3d at 367 ("The administrative record . . . need only 'indicate the determinative reason for the final action taken,' and [this court] may 'uphold a decision of less than ideal clarity if the agency's path may reasonably be discerned.'" (citation omitted) (first quoting *Camp v. Pitts*, 411 U.S. 138, 143 (1973); and then quoting *Bowman Transp., Inc.*, 419 U.S. at 286)); *see Phoenix Herpetological Soc'y, Inc. v. U.S. Fish & Wildlife Serv.*, 998 F.3d 999, 1006 (D.C. Cir. 2021) ("It is therefore permissible . . . for common sense and predictive judgements to be attributed to the

much. Eli Lilly had a surplus on hand at the end of every month in 2024, and in the month immediately prior to its Delisting Action, had an almost 11.6-million-dose surplus.

The FDA's assumption that cumulative supply and demand were zero in January 2024 (i.e., using January 2024 as the starting point) was reasonable, as Eli Lilly would not have built up a surplus during 2024 if there was still outstanding demand to meet from the months preceding January 2024. In other words, whatever supply deficit there may have been prior to January 2024, Eli Lilly's growing surplus throughout the fifteen-month period demonstrates it met all outstanding demand.

Eli Lilly's cumulative supply and demand data was not the only supply and demand data from Eli Lilly that the FDA considered in making its shortage determination. The FDA also considered biweekly stock reports from October 2024 to December 2024, Eli Lilly's inventory of finished and semi-finished reserves, Eli Lilly's production capabilities, additional product in the distribution channel, and Eli Lilly's FDA approval and production of the alternative vial form (supplementing supply of the injectable pens).

3

The Compounders argue that Eli Lilly's data "reflects shortages." They first contend that the cumulative supply and demand data contained in Tables 4 and 6 demonstrates "demand outstrips supply in each month." To make this argument, they convert the cumulative supply and demand data contained in Tables 4 and 6, to "monthly showings" by "subtract[ing] out the cumulative figures from the preceding month." But as discussed above,

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expertise of an agency in an informal proceeding, even if not explicitly backed by information in the record.").

surplus from one month may be carried over into the next month. Converting the data as Compounders have done is illogical.

The Compounders contend that Eli Lilly shipped less doses than orders received, which, they say, shows Eli Lilly is not meeting demand. In support of this argument, they convert the data contained in Table 5 to "obtain a monthly average" and compare the adjusted figures to the data in Table 4 demonstrating the orders Eli Lilly received. This is a flawed comparison. Table 4's data displays orders from wholesalers and others that Eli Lilly received. Table 5 demonstrates only what Eli Lilly shipped to wholesalers during October and November 2024. It does not factor in doses that Eli Lilly had on hand at the beginning of each month, which is part of Eli Lilly's overall supply. Table 5 also does not take into account shipments completed the month following an order, so Table 4 could include an order received in November that was not shipped until December. This could result in a discrepancy potentially as large as 720,000 doses, but it does not mean Eli Lilly was unable to meet demand.

The FDA found that Eli Lilly could "supply over 20,000,000 doses [of Mounjaro and Zepbound] per month." The Compounders contend the data actually shows Eli Lilly's "supply had never been 20 million doses a month." The FDA's finding was not unreasonable in light of Eli Lilly's investments in manufacturing capabilities and FDA approvals for single-use vials of the drugs. The FDA additionally observed that in the first two months of 2024's fourth quarter, Eli Lilly had "already supplied 28,997,000 doses of Mounjaro and Zepbound and expect[ed] to supply over 48,000,000" by the end of that quarter. The FDA concluded that "Eli Lilly's most recent projection[s for supply and demand] . . . w[ere] proven to be largely accurate and on the whole conservative; Eli Lilly generally produced more than it projected and experienced lower demand than

anticipated." The fact that Eli Lilly had not produced 20 million doses in the past does not mean that Eli Lilly is incapable of doing so in the future.

4

The Compounders argue that the "FDA brushed off all other evidence" indicating that the "shortage continued," treating conflicting evidence with a "breathtaking lack of evenhandedness." They call attention to (1) screenshots from wholesalers, (2) data taken from surveys of patients, (3) news coverage discussing the shortage situation, and (4) sales of compounded tirzepatide products.

i

The Compounders point to screenshots of wholesalers' webpages demonstrating zero or restricted supply of brand-name tirzepatide products. They criticize the FDA for discrediting the screenshot evidence as being "undated" and "not includ[ing] information about the length of time that the product is or was out of stock." They explain that many screenshots were accompanied by cover letters with dates, and at least some screenshots from one of the top United States wholesalers, Cardinal Health, contained information stating either that Eli Lilly did not provide the "expected availability in [the distribution center]," or that the "best dating available is 06/22/2025."

The FDA acknowledged that some screenshots included date information, but it ultimately concluded that the screenshot evidence did not "undermine[] or outweigh[] the evidence provided by Eli Lilly." Agencies are to "weigh evidence and determine if some evidence is reliable while other evidence is not."[74] The FDA reasoned that the majority of the screenshot

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[74] *Texas v. EPA*, 137 F.4th 353, 367 (5th Cir. 2025).

evidence did not include date information, which is correct, and that supply chain dynamics could result in particular pharmacies being unable to buy Eli Lilly's products from a particular wholesaler. The FDA reasoned that Eli Lilly provided context for some screenshots, "demonstrating that in at least those cases" the same retailer could have ordered the specific dose requested from the same wholesaler within a day or two of the screenshot demonstrating product unavailability.

The screenshots taken by retailers ordering from Cardinal Health do not alter the analysis. Although some of those screenshots stated "best dating available is 06/22/2025," it is unclear what that comment meant. The screenshots containing that language were dated December 10, 2024 and pertained to stock of Mounjaro 10mg. From that, we could surmise the "best dating available" comment meant the expiration date of the medication itself, or, as the Compounders ask us to conclude, the date on which Cardinal Health anticipated the medication being available. But Eli Lilly had 1.88 million doses of Mounjaro 10 mg in December 2024.

The FDA reasoned that the screenshots excluding the expected availability in the distribution center demonstrated that the wholesaler had the units in stock but was restricting orders for some doses to five units. The FDA explained that most products are shipped to a wholesaler's central distribution center, and the wholesaler then routes the product to one of its many forward distribution centers. Pharmacies receive product from a particular forward distribution center. When a pharmacy is unable to order product from a particular wholesaler, or a wholesaler restricts orders to certain quantities, the wholesaler could have the product in its central distribution center but has not yet routed the product to the forward distribution center from which the pharmacy receives product.

In light of the above, the FDA reasonably concluded Eli Lilly's data was more probative than the screenshot evidence suggesting a shortage persisted.

ii

The Compounders argue that the FDA did not meaningfully consider survey data it received "present[ing] tens of thousands of reports of individuals across the nation." The FDA explained in its decision that these reports had "significant limitations." It observed that data from Hims & Hers Health, Inc. was generated by internet users completing a form on its website that "anyone [could] complete," and that there were no restrictions as to the date, the internet user's location, the reason the internet user could not access the drug (such as insurance coverage or inability to obtain a prescription from a physician), or how many times the internet user could complete the form, among other things. The FDA also noted that the information it received from the Outsourcing Facilities Association (OFA), which included time-stamped reports of drug shortages that the OFA received from patients, did not state how the information was collected or other details such as why individuals were unable to access the tirzepatide products they sought, or even if the individuals who submitted information were seeking tirzepatide GLP-1 products.

The FDA further explained that concluding Eli Lilly could meet or exceed demand for tirzepatide products was not inconsistent with individuals continuing to face obstacles in obtaining those products. The FDA supported this conclusion with several reasons, including "practical dynamics of the portion of the supply chain between Eli Lilly and the individual customers," the way in which a particular pharmacy operates, and insurance coverage issues, to name a few.

iii

The Compounders contend the FDA did not address, "on the merits," news coverage and individual comments it received regarding a tirzepatide shortage. They direct us to several news articles in the administrative record, including an announcement in December 2024 that a national retail pharmacy was no longer taking new GLP-1 patients because of market demand and an earnings call in which the CEO of Cardinal Health discussed having insufficient supply of tirzepatide.

An agency "is not required to 'write an exegesis on every contention. What is required is merely that it consider the issues raised, and announce its decision in terms sufficient to enable a reviewing court to perceive that it has heard and thought and not merely reacted.'"[75] The FDA stated in its decision that it reviewed many articles, blog posts, and other news coverage. It concluded, however, that this evidence did not "outweigh the more specific, reliable, comprehensive, and current information" that Eli Lilly provided. It referred to its earlier discussion of the screenshot and survey evidence, where it recognized that supply chain dynamics, individual pharmacy operations, and insurance coverage could play a role in individuals being unable to access tirzepatide products.

The FDA acknowledged that it considered the evidence to which the Compounders point. Additionally, there is little probative value to that evidence. The December 2024 announcement the Compounders cite referred to all GLP-1 products, not just tirzepatide products. The same is true of the earnings call by Cardinal Health's CEO and many of the articles the Compounders reference. Other articles mentioned were off-topic, did

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[75] *Deep v. Barr*, 967 F.3d 498, 503 (5th Cir. 2020) (quoting *Roy v. Ashcroft*, 389 F.3d 132, 139 (5th Cir. 2004)).

not state why patients were unable to obtain tirzepatide products or acknowledged reasons for inaccessibility other than a shortage, or did not indicate whether shortages were current.

As for individual comments the FDA received, it similarly concluded that "these comments do not provide reliable evidence" nor "undermine or outweigh" Eli Lilly's evidence. The FDA explained that many comments were "substantively identical. Each such commenter identifie[d] themselves as a patient 'who ha[d] relied on compounded GLP-1 medications to effectively manage [his or her] health during the . . . shortage.'" These comments were accompanied by a "form letter asking FDA to 'keep compounded GLP-1s available for patients.'" "The form letter [did] not specify whether the commenter uses tirzepatide, semaglutide, or both; nor [did it] provide any specific evidence regarding inability to get a relevant product." Given the lack of specificity in the comments, the FDA reasonably concluded that these comments were less reliable than Eli Lilly's data.

iv

The Compounders point to sales of compounded tirzepatide as evidence of a shortage and contend the "FDA erred in disregarding" such evidence. The FDA considered sales of compounded tirzepatide, but it reasoned that "demand for the approved drug product" is different than "demand for a compounded" drug product. It explained:

> The shortage definition requires FDA to determine whether demand or projected demand for a "drug" exceeds the supply of the "drug." If the compounded drug were considered the "drug" when FDA evaluates demand, then supply of the compounded drug would necessarily also be considered part of the "supply" of the drug under the statute– a nonsensical result that would upend the role of compounding during a shortage. It would mean, for example, that if outsourcing facilities began compounding a drug during the shortage of an

> approved drug, and the supply of the compounded drug combined with the supply of the approved drug were enough to meet demand, FDA would have to end the drug shortage – a decision that would end the outsourcing facility's ability to continue compounding the drug and restart the shortage.

The FDA did, however, consider demand for compounded tirzepatide drug products "as part of [its] evaluation of projected demand for" Eli Lilly's products due to the "effect of the curtailing of compounding on demand for [Eli] Lilly's products in the future." The FDA reasoned that "some patients and health care professionals have looked to unapproved, compounded tirzepatide injection products while the FDA-approved products were in shortage" and that "curtailing of such compounding is likely to have some effect on the demand for [Eli] Lilly's products."

Based on the above, we cannot say the FDA made a "clear error of judgment" in declining to consider demand for compounded tirzepatide drug products when analyzing historical data.[76] Nor can we say the FDA made a "clear error of judgment" in recognizing that the demand for compounded tirzepatide products was relevant only to the extent that it would translate into demand for FDA-approved tirzepatide products when compounded products were no longer available. The FDA gave weight to this evidence even though it was not "clear how many patients [who used] a compounded tirzepatide injection product [would] choose to switch to [Eli] Lilly's approved" products due to the differences in price, differences in off-label use, insurance coverage, and marketing decisions by other manufactures.

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[76] *Motor Vehicle Mfrs. Ass'n, Inc. v. State Farm Ins. Co.*, 463 U.S. 29, 43 (1983) (quoting *Bowman Transp., Inc. v. Arkansas-Best Freight Sys., Inc.,* 419 U.S. 281, 285 (1974)).

The FDA did not act arbitrarily in concluding that Eli Lilly's supply would meet or exceed projected demand.[77]

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In sum, the FDA engaged in reasoned decision-making. Before crediting Eli Lilly's data, the FDA repeatedly asked Eli Lilly to explain its sources and methodologies, to supply additional information, and to respond to competing information. The FDA explained why it credited Eli Lilly's supply and demand data, and why that data supported its conclusion that Eli Lilly's supply met or exceeded demand for tirzepatide products. The FDA addressed contrary evidence submitted by the Compounders and others and explained why it found that evidence limited, anecdotal, or otherwise not probative.

For the foregoing reasons, we AFFIRM the district court's judgment.

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[77] *State Farm*, 463 U.S. at 43, 48, 52.