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United States Court of Appeals for the Fifth Circuit

United States Court of Appeals
Fifth Circuit
FILED
August 27, 2026
Lyle W. Cayce
Clerk

No. 25-10758

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

Plaintiffs—Appellants,

versus

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

Defendants—Appellees,

versus

NOVO NORDISK, INCORPORATED,

Intervenor—Appellee.

Appeal from the United States District Court
for the Northern District of Texas
USDC No. 4:25-CV-174

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

PER CURIAM:[*]

This case presents issues similar to those in *Outsourcing Facilities Association v. FDA v. Eli Lilly Company* (*Eli Lilly*),[1] which we also decide today. Both cases concern the Federal Drug Administration's (FDA's) removal of drugs from its shortage list. In *Eli Lilly*, the GLP-1 drugs Mounjaro and Zepbound, which treat diabetes and obesity, were at issue. In the present case, the GLP-1 drugs Ozempic and Wegovy, manufactured by Novo Nordisk Incorporated (Novo Nordisk), which are also used to treat diabetes and obesity, are at issue.

We affirm the district court's judgment for the same reasons we affirmed the district court's judgment in *Eli Lilly*. Any error by the FDA in not proceeding through the APA's notice and comment procedures was harmless, and the FDA's ultimate action was not arbitrary or capricious.

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.[2] Garnering FDA approval is a "long, comprehensive, and costly testing process."[3] After going through this process, Novo Nordisk received approval for its name-brand prescription drugs, Ozempic and Wegovy. It received approval for Ozempic in December 2017 and Wegovy in June 2021. These drugs, which treat type-2 diabetes and obesity, contain semaglutide, a glucagon-like peptide-1 (GLP-1) receptor agonist that helps

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

[1] *Outsourcing Facilities Ass'n v. FDA*, No. 25-10600, 2026 WL 2532081 (5th Cir. Aug. 27, 2026).

[2] *See* 21 U.S.C. § 355(a).

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

manage blood sugar levels. Novo Nordisk manufactures these drugs in a variety of dosage strengths, and patients typically start at the lowest dosage strength and, as needed, increase dosage strengths over time. Ozempic and Wegovy "are the only FDA-approved semaglutide injection products," and Novo Nordisk "is the only company that offers" them. Under 21 U.S.C. § 355(c)(3)(E)(ii), the FDA is prohibited from approving a similar drug for five years,[4] and Novo Nordisk received an additional three years of a more limited exclusivity under a different statutory provision, 21 U.S.C. § 355(c)(3)(E)(iv).[5]

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"[6] or "essentially a copy of one or more approved drugs."[7] Compounded drugs are the result of "a process by which a pharmacist or doctor combines, mixes, or alters ingredients to create a medication . . . ."[8] Compounded drugs do not undergo the "long,

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

[5] *See Outsourcing Facilities Ass'n v. FDA*, No. 4:25-CV-0174-P, 2025 WL 1239727, at *1 (N.D. Tex. Apr. 24, 2025).

[6] 21 U.S.C. § 353a(b)(1)(D).

[7] 21 U.S.C. § 353b(a)(5).

[8] *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 360-61 (2002).

comprehensive, and costly testing process"[9] that FDA-approved drugs do, but they still must meet certain statutory requirements.[10]

The FD&CA's compounding prohibition is temporarily suspended when "the drug product appears on the FDA drug shortage list."[11] 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"[12] and 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."[13]

The FDA added Wegovy to the drug shortage list on March 31, 2022, and added Ozempic to the list on August 23, 2022. Pharmacies and outsourcing facilities that met the statutory conditions were accordingly able to compound drugs to satisfy the demand for individuals who needed medication containing semaglutide. The FDA did not engage in notice-and-comment rulemaking before adding Ozempic and Wegovy to its drug shortage list.

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[9] *See* FDA, *Human Drug Compounding Laws* (Dec. 17, 2024), https://www.fda.gov/drugs/human-drug-compounding/human-drug-compounding-laws ("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.").

[10] *See* 21 U.S.C. §§ 353a, 353b; FDA, *Compounding when Drugs are on FDA's Drug Shortages List* (Aug. 8, 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.").

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

[12] 21 U.S.C. § 356e(a).

[13] 21 U.S.C. § 356c(h)(2).

Throughout the time that Ozempic and Wegovy were on the FDA's drug shortage list, the FDA "'actively monitor[ed] drug availability' and 'work[ed] to determine whether the demand or projected demand for each drug in shortage exceed[ed] the available supply.'" The FDA did this by reviewing materials Novo Nordisk, compounders, and others submitted to it. The FDA additionally "provided public updates about the status" of the "shortages on its website," where it maintained a public reporting portal for the "industry," "patients, healthcare providers, and organizations."[14] Also during this time, Novo Nordisk made significant investments to expand its production capacity to meet patient demand.

In early 2025, the FDA removed Ozempic and Wegovy from its drug shortage list, determining the "semaglutide injection product shortage . . . resolved." Just as the FDA did not engage in notice-and-comment rulemaking to place Ozempic and Wegovy on its drug shortage list, the FDA did not engage in notice-and-comment rulemaking to remove them.

The FDA issued a "Declaratory Order" and "Decision Memorandum" to memorialize its decision (the Delisting Action) and stated its "order [was] a product of an informal adjudication that included notice to affected parties via publication of the shortage determination on FDA's website, and an opportunity for affected parties to be heard by submitting information to the [FDA] for consideration." The FDA stated in its Declaratory Order that it "reviewed information provided . . . by Novo Nordisk, the manufacturer of the relevant semaglutide injection products."

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[14] *See, e.g.*, 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; FDA, *Drug Shortages* (July 15, 2026), https://www.fda.gov/drugs/drug-safety-and-availability/drug-shortages.

This information included "data regarding Novo Nordisk's production and inventory of [the semaglutide injection] products, such as quantities supplied and demanded, and inventory held in stock, for all strengths of these drug products; projected supply and demand in future months; and wholesaler inventory data." The FDA "also considered information from multiple sources other than Novo Nordisk, including telehealth companies, pharmacy compounders, associations representing pharmacy compounders and outsourcing facilities, and individuals."

The FDA concluded Novo Nordisk's data had more probative value than the other information it reviewed. Specifically, the FDA stated that the other information had "important limitations" that did "not undermine or outweigh the evidence demonstrating that Novo Nordisk's supply is currently meeting or exceeding demand" and that "it will meet or exceed projected demand." The FDA stated that, "[t]o avoid unnecessary disruption to patient treatment and to help facilitate an orderly transition," subject to certain requirements, it would not take action against compounders within either 60 or 90 days of its decision, depending on the type of compounder.

Outsourcing Facilities Association and North American Custom Laboratories, LLC (the Compounders) filed this lawsuit under the APA and subsequently moved for a preliminary injunction to prevent the FDA's Delisting Action from taking effect. Novo Nordisk intervened as a defendant. In the Compounders' motion for a preliminary injunction, they argued that the "FDA unlawfully promulgated the delisting action by failing to undertake notice and comment" and that "the delisting action is arbitrary

and lacks a reasoned basis." The district court denied the motion for a preliminary injunction.[15]

Regarding the Compounders' notice-and-comment argument, the district court "fully adopt[ed]" its "reasoning and conclusion" from its decision in *Eli Lilly*, explaining that the Compounders' "arguments . . . [were] the same ones they raised on this issue" when moving for a preliminary injunction in that case.[16] It also pointed out that its decision in *Eli Lilly* was one that "the Fifth Circuit seemingly agree[d] with."[17] That was because the Compounders appealed the district court's preliminary injunction decision in *Eli Lilly*, and a panel of this court decided that the Compounders "ha[d] not made their 'clear showing'" that they would be likely to succeed on the merits for "the reasons given by the district court in its thorough opinion explaining its denial of a preliminary injunction." Regarding the Compounders' arbitrary and capricious argument, the district court concluded that the Compounders were "not likely to succeed" on the merits.[18]

The Compounders did not appeal the district court's denial of the preliminary injunction in this case, and the parties cross-moved for summary judgment. The district court rejected the Compounders' notice and comment and arbitrary and capricious arguments and entered summary

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[15] *Outsourcing Facilities Ass'n v. FDA*, No. 4:25-CV-0174-P, 2025 WL 1239727, at *1 (N.D. Tex. Apr. 24, 2025).

[16] *Id.* at *4.

[17] *Id.*

[18] *Id.* at *8.

judgment in favor of the FDA and Novo Nordisk.[19] The district court entered final judgment, and the Compounders timely appealed.

II

The Compounders bring two issues on appeal. First, they argue that the Delisting Action was unlawful because the FDA violated the APA by not subjecting its Delisting Action to notice and comment. Second, they argue that, even if the FDA lawfully proceeded through adjudication, the Delisting Action was arbitrary and capricious. "This court reviews the district court's grant of summary judgment *de novo*." [20]

As in the *Eli Lilly* case, we need not decide whether the FDA erred in not subjecting its Delisting Action to notice and comment because any such error was harmless. We further conclude that that the FDA's Delisting Action was not arbitrary or capricious.

III

Most of the parties' arguments in this case are similar to those in *Eli Lilly*, so we do not replicate our decision on those issues here. But the parties raise an argument not at issue in *Eli Lilly*, and that is what deference this court affords an agency's characterization of its own action.

The FDA points out that this court stated in *City of Arlington* that it "accord[s] significant deference to an agency's characterization of its own action." [21] The Compounders counter that this court affords only "minimal"

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[19] *Outsourcing Facilities Ass'n v. FDA*, No. 4:25-CV-0174-P, 2025 WL 1697270, at *1-6 (N.D. Tex. June 13, 2025).

[20] *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)).

[21] *City of Arlington v. FCC*, 668 F.3d 229, 240 (5th Cir. 2012) (quoting *Am. Airlines, Inc. v. Dep't of Transp.*, 202 F.3d 788, 797 (5th Cir. 2000)), *aff'd*, 569 U.S. 290 (2013).

deference, citing this court's later decision in *W & T Offshore.*[22] In *W & T Offshore*, this court stated that the "Fifth Circuit may accord 'some deference' to 'the agency's characterization of its own rule,'" but "this deference is minimal."[23] There may be some tension between these decisions. Nevertheless, the amount of deference this court affords to an agency's characterization of its own action is not necessary to resolve this appeal. As in *Eli Lilly*, we need not decide here whether the FDA proceeded by rulemaking or adjudication, nor whether it abused its discretion in so proceeding, because "any failure by [the FDA] to comply with the APA in this case was harmless."[24]

IV

"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 substance of decision reached.'"[25] 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

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[22] *W & T Offshore, Inc. v. Bernhardt*, 946 F.3d 227, 237 (5th Cir. 2019).

[23] *Id.* (quoting *Pros. & Patients for Customized Care v. Shalala*, 56 F.3d 592, 595 (5th Cir. 1995)).

[24] *City of Arlington*, 668 F.3d at 243.

[25] *Id.* at 243-44 (quoting *U.S. Steel Corp. v. EPA*, 595 F.2d 207, 215 (5th Cir.1979)).

> circumstances in which the error arises may well make all the difference." [26]

Novo Nordisk argues that the lack of notice-and-comment did not prejudice the Compounders. The Compounders respond that the error affected the procedure used and therefore the harmless error doctrine is inapplicable. They also point out that the FDA did not join Novo Nordisk in raising this argument and that interested persons were "in the dark" about the FDA's approach because it did not "publish the standards it would apply to evidence submitted" and the FDA's decision involving tirzepatide (the active ingredient in Eli Lilly's drugs Mounjaro and Zepbound) "disclosed nothing relevant."

"The APA's notice-and-comment procedures are familiar: 'Under the APA, agencies issuing rules must publish notice of proposed rulemaking in the *Federal Register* and shall give interested persons an opportunity to participate in the rule making by allowing submission of comments.'" [27] However, publication in the Federal Register is unnecessary if the "persons subject" to its action "ha[d] actual notice." [28] "In addition, the APA requires that publication of a substantive rule shall be made not less than 30 days before its effective date." [29]

The FDA's decision not to subject its Delisting Action to notice and comment "had no bearing on the procedure used or the substance of decision reached." [30] The record confirms the Compounders had actual notice and an

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[26] *Id.* at 244 (quoting *Shinseki v. Sanders,* 556 U.S. 396, 411-12 (2009)).

[27] *Id.* (quoting *United States v. Johnson*, 632 F.3d 912, 927 (5th Cir. 2011)).

[28] 5 U.S.C. § 553(b).

[29] *City of Arlington*, 668 F.3d at 244 (quoting *Johnson*, 632 F.3d at 927).

[30] *Id.* at 243-44 (quoting *U.S. Steel Corp.*, 595 F.2d at 215).

opportunity to comment,[31] and the FDA gave notice that its decision would not have effect until sixty or ninety days after it issued the order. The harmless-error doctrine therefore applies, and the burden is on the Compounders to show "it is clear that the lack of notice and comment . . . prejudice[d]" them.[32] They do not make that showing.

Although the FDA did not publish a notice in the Federal Register, it did publish updates on its website about the status of semaglutide products. On October 2, 2024, roughly four months before its February 21, 2025 Declaratory Order memorializing the Delisting Action, the FDA posted that semaglutide injections products were in shortage but that Novo Nordisk "ha[d] reported all but one of the presentations are available."[33] On December 19, 2024, about two months before its Declaratory Order, the FDA posted that Novo Nordisk "ha[d] reported all presentations are available."[34] Throughout this time, the FDA maintained a public reporting portal through which it received and considered information potentially relevant to supply and demand for semaglutide injection products. The Compounders submitted at least 34 separate comments to the FDA "for the

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[31] *See U.S. Telecomm. Ass'n v. FCC*, 825 F.3d 674, 725 (D.C. Cir. 2016) ("A deficiency of notice is harmless if the challengers had actual notice") (citing *Small Refiner Lead Phase-Down Task Force v. EPA*, 705 F.2d 506, 549 (D.C. Cir. 1983)).

[32] *City of Arlington*, 668 F.3d at 244 (quoting *Johnson*, 632 F.3d at 931); *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)).

[33] 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.

[34] FDA, *FDA Clarifies Policies for Compounders as National GLP-1 Supply Begins to Stabilize* (Dec. 19, 2024), https://www.fda.gov/drugs/drug-alerts-and-statements/fda-clarifies-policies-compounders-national-glp-1-supply-begins-stabilize.

administrative record." For example, on October 23, 2024, the Compounders sent the FDA an email with an article regarding the "shortages of GLP-1s and the prices people are being charged." On October 30, 2024, the Compounders sent the FDA an email stating "[f]or the . . . drug shortage list, I wanted to provide you a copy of this 483 from FDA that was issued to the plant that manufactures semaglutide for Novo." The Compounders continued to send information to the FDA until February 5, 2025. In their last email, the Compounders "[a]ttached . . . PDFs containing evidence of an ongoing [s]emaglutide shortage." The Compounders submitted information to the FDA over more than a three-month period—longer than the thirty-day-minimum comment period this court has said the APA requires.[35]

The FDA's failure to "declare that it 'was soliciting comments from all interested parties'" on its website postings does not demonstrate how the Compounders themselves were prejudiced.[36] As outlined above, the parties involved had notice of the FDA's continued monitoring of the semaglutide injection shortage,[37] and numerous opportunities to submit information to

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[35] *See Chamber of Com. of U. S. v. SEC*, 85 F.4th 760, 779 (5th Cir. 2023) ("the APA generally requires only a minimum thirty-day comment period"); *see also* FDA, *Drug Shortages* (July 15, 2026), https://www.fda.gov/drugs/drug-safety-and-availability/drug-shortages (providing access to drug shortage notifications and explaining how to submit information to FDA regarding drug shortage status information).

[36] *See City of Arlington*, 668 F.3d at 245-46 (recognizing that the parties complaining about FCC's failure to go through notice-and-comment rulemaking was harmless because they had "ability to comment"); *Johnson*, 632 F.3d at 931 ("[W]hen a party's claims were considered, even if notice was inadequate, the challenging party may not have been prejudiced."); *see also U.S. Telecom Ass'n*, 825 F.3d at 725 ("A deficiency of notice is harmless if the challengers had actual notice . . . or if they cannot show prejudice in the form of arguments they would have presented to the agency if given a chance.").

[37] *See U.S. Telecom Ass'n*, 825 F.3d at 725 (recognizing that "if the challengers had actual notice," lack of formal notice is "harmless").

the FDA.[38] The FDA received numerous submissions from others, including telehealth companies, pharmacy compounders, associations representing pharmacy compounders, and individuals.

The Compounders' argument that the FDA did not "disclose" its measures of supply and demand leaving them "in the dark" about the FDA's approach is unpersuasive. The FDA followed the statutory framework, applying the statutory definition of shortage to the evidence before it. Its December 2024 decision involving Eli Lilly's tirzepatide-injection products set forth its methodology and identified the kinds of evidence it considered less probative.

The Compounders do not identify any additional information they would have submitted had the FDA published a formal notice or disclosed its methodology or other information at a different date or in a different manner.[39] If the FDA's decision not to proceed with a notice-and-comment rulemaking was erroneous under the APA, an issue we do not resolve, any error was harmless.

V

"The APA instructs courts to set aside agency action that is 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance

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[38] *See City of Arlington*, 668 F.3d at 244-45 (concluding FCC's proceeding by adjudication was harmless when it "received and considered comments from dozens of interested parties").

[39] *See id.* (recognizing that parties did not demonstrate prejudice when they "suggested no reason why [the APA's thirty-day] waiting period was needed"); *U.S. Telecom Ass'n*, 825 F.3d at 725 ("A deficiency of notice is harmless if the challengers . . . cannot show prejudice in the form of arguments they would have presented to the agency if given a chance.") (citing *Owner-Operator Indep. Drivers Ass'n v. Fed. Motor Carrier Safety Admin.*, 494 F.3d 188, 202 (D.C. Cir. 2007)).

with law.'"[40] "Agency decisions are 'presumptively valid.'"[41] "The scope of review under the 'arbitrary and capricious' standard is narrow and a court is not to substitute its judgment for that of the agency."[42] But an agency "must examine the relevant data and articulate a satisfactory explanation for its action . . . ."[43] "In reviewing that explanation, [this court] must consider whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment."[44] Ultimately, "[a]rbitrary and capricious review focuses on whether an agency articulated a rational connection between the facts found and the decision made."[45] "Illogic and internal inconsistency are characteristic[s] of arbitrary and unreasonable agency action."[46]

The Compounders contend the FDA's Delisting Action was arbitrary and capricious because it (1) did not "choose and justify parameters for analysis," and (2) arbitrarily resolved the drug shortage in the face of evidence that a shortage persists. We disagree.

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[40] *Mexican Gulf Fishing Co. v. U.S. Dep't of Com.*, 60 F.4th 956, 971 (5th Cir. 2023) (quoting 5 U.S.C. § 706(2)(A)).

[41] *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)).

[42] *Motor Vehicle Mfrs. Ass'n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

[43] *Id.*

[44] *Mexican Gulf Fishing Co.*, 60 F.4th at 971 (quoting *Texas v. EPA*, 983 F.3d 826, 835 (5th Cir. 2020)).

[45] *Id.* (quoting *ExxonMobil Pipeline Co. v. U.S. Dep't of Transp.*, 867 F.3d 564, 571 (5th Cir. 2017)).

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

A

The Compounders contend FDA did not "disclose what 'period of time' [it] chose to analyze, or its parameters of supply and demand," but "reprint[ed] data Novo Nordisk provided," which had "substantial holes and obvious questions" that the FDA did not answer. The Compounders further contend that the FDA "did not justify the parameters [or] identify reasons for rejecting alternatives."

The FDA disclosed its "period of time" parameters. It made clear in its Declaratory Order that it considered data between September 2024 and February 2025, as well as projected demand data for February 2025 and March 2025. Every table and figure containing data the FDA considered was within this time period, and, in the district court, the Compounders conceded this point.

The FDA's justification for considering data from several months leading up to its Delisting Action, and projected data for the two months after its Delisting Action, does not contravene the FD&CA. The FD&CA requires the FDA to maintain an "up-to-date"[47] 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 exceeds the supply of the drug."[48] The data the FDA considered was "up-to-date" given it was from the months immediately prior to, and two months following, its Delisting Action. Since this was consistent with the statutory mandate, the FDA did not need to otherwise "justify" its time-period parameters. "The administrative record . . . need only 'indicate the determinative reason for

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[47] 21 U.S.C. § 356e(a).

[48] 21 U.S.C. § 356c(h)(2).

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.'" [49]

Nor did the FDA use "completely different parameters" when it considered data that spanned a longer period of time than that scrutinized in *Eli Lilly*. In both decisions, the FDA considered relatively recent data that could reasonably be considered as fulfilling its statutory mandate to maintain an "up-to-date" drug shortage list.[50]

Regarding the parameters for supply and demand, the Compounders take issue with the the FDA's consideration of Novo Nordisk's data demonstrating its (a) "net inventory balance," (b) "average inventory," (c) "days on hand," (d) "cumulative supply and demand," and (e) "information about wholesalers." Aside from raising concerns about the data itself, the Compounders contend that the "FDA did not defend" its decision to rely on that data "*in* its Decision."

The "grounds upon which an administrative order must be judged are those upon which the record discloses its action was based."[51] As stated earlier, we "may 'uphold a decision of less than ideal clarity if the agency's

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[49] *Pension Benefit Guar. Corp. v. Wilson N. Jones Mem'l Hosp.*, 374 F.3d 362, 367 (5th Cir. 2004) (internal 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)).

[50] *See Sierra Club v. U.S. Dep't of Interior*, 990 F.3d 898, 908 (5th Cir. 2021) (providing that when a statute "does not define how to measure" a standard by which the agency is to act, the agency may render a conclusion "based on its own expertise").

[51] *Louisiana v. U.S. Dep't of Energy*, 90 F.4th 461, 469 (5th Cir. 2024) (quoting *SEC v. Chenery Corp.*, 318 U.S. 80, 87 (1943)); *see also Dep't of Homeland Sec. v. Regents of Univ. of Cal.*, 591 U.S. 1, 21 (2020) ("When an agency's initial explanation 'indicate[s] the determinate reason for the final action taken,' the agency may elaborate later on that reason . . . .") (first alteration in original) (quoting *Camp*, 411 U.S. at 143)).

path may reasonably be discerned.'"[52] While "an agency must 'disclose the basis' of its action,"[53] it "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.'"[54] The FDA did so here.

The Compounders argue it is "peculiar" that Novo Nordisk's net inventory balance was taken from a "single day" without disclosing "why that particular day," January 16, 2025, was selected. The FDA and Novo Nordisk respond that this contention is without merit as it ignores the rest of the FDA's decision analyzing months of data and does not explain how "considering a detailed snapshot of inflows and outflows in a particular day is itself unreasonable." Novo Nordisk additionally notes that the FDA's consideration of its net inventory balance on that day was the "most up-to-date snapshot that Novo Nordisk had at the time that FDA asked for it."

Contrary to the Compounders' assertion, the FDA and Novo Nordisk's response is not a post-hoc justification. The FDA's path may reasonably be discerned here in light of the statutory mandate to maintain an "up-to-date" drug shortage list, along with information from the administrative record.

The record discloses that Novo Nordisk submitted its net inventory balance data on this particular day as part of its response to the FDA's "drug

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[52] *Pension Benefit Guar. Corp.*, 374 F.3d at 367 (quoting *Bowman Transp., Inc.*, 419 U.S. at 286).

[53] *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, 167-69 (1962)).

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

shortages questions dated January 16, 2025," about a month prior to its Delisting Action. The FDA asked for average inventory data from January 16 in a series of correlated questions addressing "the quantity of Ozempic and Wegovy held in inventory for the U.S. Market." Novo Nordisk submitted data for its "Net Inventory Balance of finished product . . . during Q4 2024," its "current inventory," "open orders," and "net inventory balance" on January 16, 2025, "the volume of units shipped to wholesalers by month for" Q4 2024, and "the average daily wholesaler inventory for each dose strength of Wegovy and Ozempic" for Q4 2024. The FDA considered data from this "single day" alongside data from the most recent quarter, Q4 2024. The FDA cited this series of questions and responses in connection with the net inventory balance data in its Decision Memorandum. Given the context in the record, the amount of other data the FDA considered, and the statutory mandate, it was not unreasonable for the FDA to consider inventory data from this particular day.

Table 2 in the FDA's Decision Memorandum displayed four months of Novo Nordisk's average inventory data (from October 2024 to January 2025), which comprised "inventory at Novo Nordisk's U.S. Warehouse, in-transit, and/or manufacturing sites, by dosage strength." The Compounders criticize the FDA for considering "average inventory" instead of the "standard means of inventory accounting," which considers beginning inventory, purchases during a set time period, and ending inventory, and they argue that the FDA did not justify using such a metric. They also contend including "in-transit" product as part of the supply was improper, and that over a month, a single package could be in all three places at once (the warehouse, in-transit, and a manufacturing site), resulting in a "triple count[ing]" of packages that make it to all three sites during the month.

The FDA did not act arbitrarily and capriciously in considering the data in Table 2. The Compounders fail to recognize that the FDA did

consider their preferred "standard means of inventory accounting." It reviewed Novo Nordisk's inventory and stock levels, as well as wholesaler and customer orders over the same period for which it considered Novo Nordisk's average inventory. Also, the FDA "'disclose[d] the basis' of its action."[55] It explained that the average inventory showed "the amount of finished product on average in a given month [that Novo Nordisk] maintained in stock after all open orders from all customers had been filled" and "demonstrate[d] that Novo Nordisk is filling wholesaler orders and maintaining product in inventory net of open orders."

The Compounders assertion that the FDA should not have considered in-transit product as part of Novo Nordisk's supply belies an ordinary understanding of supply-chain dynamics—inventory at various stages of the supply chain may be used to meet demand. The record demonstrates as much. In response to the FDA's drug shortage questions, Novo Nordisk noted that it takes only two days for finished product to move from a Novo Nordisk U.S. manufacturing site to a Novo Nordisk warehouse, and it described supply in its warehouses, in-transit, and at its manufacturing facilities as "ready to fill orders."

Regarding the Compounders' contention that the FDA did not address the possibility of "triple-counting," the district court ably explained the fallacy in this argument.[56] Novo Nordisk submitted data from a period of several months that demonstrated an overall trend that Novo Nordisk's inventory was increasing each month. Inventory for Novo Nordisk's U.S. warehouses did not include in-transit or manufacturing-site inventory. The

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[55] *Dep't of Com. v. New York*, 588 U.S. at 780 (quoting *Burlington Truck Lines, Inc.*, 371 U.S. at 167-69).

[56] *See Outsourcing Facilities Ass'n v. FDA*, No. 4:25-CV-0174-P, 2025 WL 1239727, at *6 (N.D. Tex. Apr. 24, 2025).

data included in Table 2 was calculated using daily measurements of Novo Nordisk's inventory: to calculate the average inventory for each month, Novo Nordisk added its daily dosage inventory for every day of that month, and then divided the total by the number of days in that month. For every daily dosage inventory used in this calculation, "a dose [could] only be in one location."[57] "This procedure," the district court explained, "prevent[ed] doses from being over counted."[58]

The Compounders contend that the FDA's decision "report[ing] '*days* on hand' by *week* . . . raises unanswered questions, such as when the daily measure is taken and how it is converted for weekly reporting." They complain that these parameters are "unexplained and unjustified." They also argue that the FDA's transcription error copying a different data point in Table 3—the table displaying days on hand data—for two weeks in October 2024, out of seven weeks of data spanning from September 2024 to January 2025, suggests the FDA considered the incorrect information.

The FDA thoroughly explained Novo Nordisk's days-on-hand measurement by considering the parameters Novo Nordisk used. The FDA stated that days-on-hand data included "finished products . . . in Novo Nordisk's warehouse in the US and units at the wholesalers in the US'" but did not include "semi-finished products at Novo Nordisk production sites," nor "finished products at retailers and pharmacies." The FDA explained that the "days on hand" data was measured "by dosage strength" and "refer[red] to the number of days of stock at a given point in the supply chain." "For example, if [Novo Nordisk] say[s] that [it] ha[s] 10 Days On Hand (DOH) for a specific dose of Wegovy, [that] means [it] ha[s] stock that

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[57] *Id.*

[58] *Id.*

will serve 10 days of demand from all customers." The FDA said that days on hand was calculated by "Stock on hand (in packs or pieces) / Average Daily Demand (in packs or pieces)," and "Average Daily Demand [was] calculated using Novo [Nordisk's] demand projections (in packs or pieces) over the following one month divided by 30 days." "[A]verage daily demand" referred to "Novo Nordisk's demand projections, not total prescriptions fulfilled," and "demand projections for this measure [were] based on total prescriptions fulfilled at pharmacies, assumptions about internal and external events, and an upward adjustment for wholesaler/customer and pharmacy/retailer stock." Furthermore, its days on hand metric was not a "daily measure" converted for "weekly reporting"; it measured Novo Nordisk's inventory at a particular time each week. Throughout the FDA's description of the days on hand data, it consistently cited to the data without transcription errors. Regardless, the FDA did not refer to Table 3 for the incorrect October 2024 data that it contained, but for its correct January 2025 data. Referencing Table 3, the FDA concluded that in "January 2025, Novo Nordisk stated that it had at least 30 days of finished product on hand for each strength of Ozempic and Wegovy, and significantly more for most strengths of those products." In other words, the transcription error is irrelevant.

The Compounders take issue with the data presented in Figures 1 and 2. They argue the "cumulative method of counting is arbitrary" because it "depends on arbitrary points like the choice of start dates," and they condemn the use of realized sales as a measure of demand because such a measure "assumes away the possibility of a shortage." They advance a similar argument for using filled prescriptions as a measure of demand in Table 8.

"An agency's choice to proceed on the basis of 'imperfect' information is not arbitrary and capricious unless 'there is simply no rational

relationship' between the means used to account for any imperfections and the situation to which those means are applied."[59] The FDA recognized the limitations in considering the data in Figures 1 and 2 and Table 8, but it reasonably determined that such data was still relevant. The "start date" for the cumulative data in Figures 1 and 2 was consistent with its statutory mandate, as described above, and the FDA relied on this data to affirm its conclusion that "supply [wa]s outpacing demand," which it had derived from other data it considered. The FDA recognized that filled prescriptions did "not account for unfilled prescriptions due to lack of supply" but concluded that comparing the filled prescription data "to the data [Novo Nordisk] provided" about packages "supplied from national wholesalers to retailers/pharmacies" was still helpful since it "tend[ed] to indicate that unfilled prescriptions [were] not due to a lack of nationwide product availability." As for its consideration of realized sales, such data was at least partially relevant since the number of people who purchase a product indicates at least the starting point and perhaps the end point of the number of people who want the product. Given the FDA did not rely exclusively on this data, recognized its limitations, and explained why considering it was still relevant, the FDA did not act arbitrarily and capriciously in this regard.

The Compounders call into question Novo Nordisk's data concerning wholesalers because Novo Nordisk received each wholesaler's information on a weekly basis, combined that information, and supplied the monthly average of the wholesalers' weekly inventories to the FDA. The Compounders suggest Novo Nordisk could "hide" information through its combination of wholesaler data and conversion to an average.

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[59] *Tex. Oil & Gas Ass'n v. EPA*, 161 F.3d 923, 935 (5th Cir. 1998) (quoting *Am. Iron & Steel Inst. v. EPA*, 115 F.3d 979, 1004 (D.C. Cir. 1997)).

There is nothing inherently suspicious about converting weekly data to a monthly average. The record demonstrates that the FDA requested Novo Nordisk provide this data "by month."

The Compounders also question the integrity of this data by comparing Figures 1 and 2 with Tables 4 and 5 in the FDA's decision. They point out that the realized sales numbers in Tables 4 and 5 do not match the realized sales numbers in Figures 1 and 2. To reach this conclusion, however, the Compounders "convert[]" the demand numbers in Figures 1 and 2 to "monthly" numbers and conclude that "they exceed the supply figures" of Tables 4 and 5 "by a large margin."

This purported discrepancy is a red herring. Though these metrics are related, they are distinct, and it is therefore not surprising that the data is not identical. Tables 4 and 5 used daily sums to represent the total quantity supplied by Novo Nordisk to wholesalers and other customers, and included Novo Nordisk's inventory of finished and semi-finished product. Figures 1 and 2 used weekly sums to represent "finished product supplied (or expected to be supplied) from the Novo Nordisk production sites to the Novo Nordisk . . . US Warehouse," and excluded Novo Nordisk's "inventory of finished and semi-finished product."

B

The Compounders argue that the FDA arbitrarily concluded that the shortage had ended because the evidence demonstrated that a "shortage persist[ed]." They contend (i) Novo Nordisk did not satisfy all wholesaler orders for Wegovy, (ii) Novo Nordisk "was candid about a drug shortage outside its direct conversations with FDA," (iii) the record revealed that Novo Nordisk would be unable to meet demand after compounded drug products were unavailable, and (iv) the FDA improperly dismissed other evidence of a shortage.

The Compounders point to Table 5 in the FDA's decision, which demonstrates supply and demand of Wegovy by dosage strength. The Compounders first argue Table 5 demonstrates a shortage persisted because it reveals that Novo Nordisk did not meet the quantity of the lowest three doses of Wegovy that wholesalers requested in October 2024, November 2024, or December 2024 (fall 2024). The Compounders next contend Novo Nordisk's discussion about dosage titration—the process by which an individual gradually increases their dosage of a medication over a period of time—contradicted its discussion about wholesaler overordering during fall 2024 making the FDA's decision illogical and internally inconsistent.

The FDA addressed Novo Nordisk's purported lack of supply. It described in its decision that wholesalers were artificially driving up demand during fall 2024 by engaging in hoarding behavior, and that Novo Nordisk adjusted the amount it supplied to wholesalers to meet actual demand, which caused the data to suggest a shortage existed when it did not:

> Following a period of limited availability for an approved drug, wholesaler system-generated orders are significantly higher even though downstream orders may not even exist or be anticipated. In the case of Wegovy, when Novo Nordisk reported to FDA in fall 2024 that the three lowest dosage strengths were available, wholesalers' system-generated orders were significantly higher, reflecting repeated orders added to [Novo Nordisk's] systems and rolled over between October to December 2024 . . . . [This] generated a large number of duplicate orders which were far in excess of actual market demand . . . . Novo Nordisk discussed this matter with the wholesalers [, and they worked together] to assess their outflow (from wholesaler to retailers and pharmacies) and inventory levels and "right size[d]" the supply to prevent overstocking in specific distribution channels . . . . Novo Nordisk [pointed

> out] . . . that even when [it] increased the supply in December [2024] for the lowest 3 doses of Wegovy as compared to November, the inventory of the wholesalers increased, which demonstrate[d] that the wholesalers were overstocking . . . [and] the increased supply was not needed to satisfy demand.

The FDA cited a series of questions and answers between it and Novo Nordisk to support its analysis. In January 2025, the FDA asked Novo Nordisk to provide data dating from October 2024, by month, for the quantity of units wholesalers requested for each strength of Ozempic and Wegovy. Novo Nordisk, explaining this data, stated that it fulfilled all orders for all strengths of Ozempic and the two higher strengths of Wegovy, but for the three lower dose Wegovy strengths, it adjusted the quantities it supplied to "ensure patients who initiate their treatment can continue with their treatment regimen" and to "align with actual demand." It explained that the status in the FDA's drug shortage database for the lowest three doses of Wegovy had changed from "limited availability" to "available" at the start of fall 2024, which caused excess orders from wholesalers during fall 2024. The FDA asked Novo Nordisk to describe how it determined what orders were "duplicates." Novo Nordisk responded that it determined the "right" amount to supply to wholesalers to meet demand of the three lowest doses of Wegovy by ensuring (1) wholesalers had enough supply to meet demand downstream, (2) wholesalers could maintain inventory throughout the following week, and (3) the quantity supplied of the three lowest doses was consistent across wholesalers. It then demonstrated in a table that, by January 2025, wholesaler systems were "able to finally reconcile and remove excess orders," and there were no unfulfilled excess orders in January 2025. The FDA asked Novo Nordisk how it ensured the number of patients who initiated treatment could continue with their treatment regimen when making these quantity adjustments. Novo Nordisk stated: "Every time

[Novo Nordisk] suppl[ies] a wholesaler with a starter dose (0.25mg), [it] ensure[s] the wholesaler also has an aligned amount of titration doses (0.5mg and 1mg) and maintenance doses . . . so that new patients that initiate treatment with the starter dose can continue through the titration doses and onto the maintenance doses."

Furthermore, the FDA recognized in its decision that Novo Nordisk fulfilled all orders of Wegovy in January 2025 without adjustment for wholesaler overordering, that Novo Nordisk had no backorders since October 2024, which occur "when an order cannot be fulfilled at the time of purchase because the product is not in Novo Nordisk's current stock," and that Novo Nordisk "reported building up substantial stock of finished product and semi-finished product, not counted as part of supply [in Table 5]."

In light of the record, the FDA did not act arbitrarily in this regard. The FDA's conclusion that Novo Nordisk appropriately adjusted the quantity it supplied to wholesalers does not contradict its conclusion that wholesalers were artificially driving up demand by submitting system-generated duplicate orders for the lowest three doses of Wegovy. The titration discussion merely explained how Novo Nordisk ensured that patients who initiated treatment could continue with their treatment regimen despite Novo Nordisk's quantity adjustments made in response to excess orders.

2

The Compounders point to two comments Novo Nordisk's then-CEO, Lars Fruergaard Jorgensen, made in a November 2024 interview with Reuters to demonstrate Novo Nordisk "admitted" a shortage. They criticize the FDA for not addressing these comments in its decision.

In the interview, Jorgensen stated: "We still have a situation where there are far more patients who would like to have the treatment than what both Lilly," the manufacturer of tirzepatide products, "and [Novo Nordisk] can supply." He also stated: "[W]e'll . . . see more volumes going into the U.S. market because we see an intact demand there, and we're far from saturating that demand." The Compounders argue these comments were "corroborated" by Cardinal Health's CEO, who was asked about inventory issues concerning GLP-1 drugs and responded that "there's a lot of volatility in terms of strong demand [and] supply that does not meet that demand."

The FDA's failure to specifically mention Jorgensen's comments in its decision does not make its Delisting Action arbitrary and capricious.[60] The FDA stated in its decision that it "reviewed various articles," "blog posts," and "other news coverage," and concluded that they did not "contain probative evidence . . . to determine whether a shortage has resolved." The Compounders' "assertion that [the FDA] did not consider this evidence because [it] did not specifically cite certain articles . . . cannot overcome the presumption of regularity."[61] This is especially true here when the record demonstrates that the FDA inquired about Jorgensen's comments, and the comments are isolated and stripped of their context. The Compounders retrieved Jorgensen's comments from a Reuters news article on "Wegovy prices, supplies and compounding" that "highlight[ed]" comments he made during a Reuters interview.

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[60] *See Deep*, 967 F.3d at 503.

[61] *Id.* (citing *Nicholson v. Brown*, 599 F.2d 639, 649 (5th Cir. 1979)); *see also Huawei Techs. USA, Inc. v. FCC*, 2 F.4th 421, 449 (5th Cir. 2021) ("Although the FCC could have done more, under our 'narrow and highly deferential' standard of review, it did enough.") (quoting *Sierra Club v. EPA*, 939 F.3d 649, 672 (5th Cir. 2019)).

Regardless, these comments do not suggest the FDA unreasonably concluded the shortage had resolved. The first comment concerned all GLP-1 products, not just Ozempic and Wegovy, as demonstrated by Jorgensen's reference to Eli Lilly. It also "refer[red] to the global market for these treatments, not the US market specifically." The second comment regarding "saturating" demand "refer[red] generally to the need for diabetes and obesity treatments, not the specific demand for Ozempic and Wegovy products." Insofar as Cardinal Health's CEO "corroborat[ed]" Jorgensen, he was addressing supply and demand for all GLP-1 products, not just Ozempic and Wegovy.

3

The Compounders argue the record demonstrates that Novo Nordisk would be unable to meet demand after compounded drugs become unavailable due to transitional demand—"demand from those switching from compounded products to Novo Nordisk's medicines." They point to a presentation Novo Nordisk provided to the FDA in which it cited a CNN article to support its proposition that "[a]nalysts estimate that around 20% of all prescriptions of GLP-1 RAs are for compounded versions of these drugs." The Compounders contend that, had the FDA considered this 20% figure, it would have concluded Novo Nordisk did not have sufficient supply to satisfy total market demand.

The FDA adequately considered transitional demand and "announce[d] its decision in terms sufficient to enable [us] to perceive that it has heard and thought and not merely reacted."[62] The FDA reviewed information outsourcing facilities sent, as required by law, and provided a table and analysis of that information in its decision. This information

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

demonstrated that the outsourcing facilities produced 310,000 packages of semaglutide products per month. FDA also reviewed information the Alliance for Pharmacy Compounding (APC) voluntarily sent regarding pharmacy and physician compounders, who are not required to report to the FDA like the outsourcing facilities. It assumed for the purposes of its decision that the quantities APC reported were accurate and added 170,000 to the 310,000 mentioned above. The FDA considered that "Novo Nordisk reported that it is able to supply 5.8 million packages of its semaglutide injection products per month" and that "its most recent stock report shows that its current inventory contain[ed] 13.6 million fully finished packages and another 21.2 million semi-finished packages." The FDA then concluded: "Even assuming that all [the packages of semaglutide injection products the outsourcing facilities reported producing would] have been supplied to the market and, upon the curtailing of compounding, would translate to demand for Novo Nordisk's products, this would represent a small amount relative to Novo Nordisk's production and inventory"; the "total amount," 520,000, "remains small relative to Novo Nordisk's production and inventory."

The FDA also concluded that "it [was] not reasonable to project [the] demand for compounded products . . . as one-for-one demand for Novo Nordisk's approved products" because (1) price differentials exist between Novo Nordisk's approved products and compounded drugs, (2) compounded drugs are being used for different medical conditions than the FDA-approved use of Novo Nordisk's products, (3) compounded drugs sometimes contain different formulations from Novo Nordisk's products, and (4) marketing decisions other manufacturers may make in response to the Delisting Action could affect demand. There was no clear error of judgment here.

Furthermore, the FDA did not need to address expressly the 20% figure from CNN that the Compounders argue would have changed the outcome. The record reveals that the FDA did consider that estimate, even though it did not discuss it in its Delisting Action. That figure, which took into account the overall market for GLP-1 medicines,[63] did not capture the relevant market. Additionally, just because Novo Nordisk used this figure in a presentation to the FDA about compounded semaglutide does not mean Novo Nordisk itself "estimated that 20% of the market was satisfied by compounders." But even if it had, such a figure would only be partially relevant to the FDA's shortage determination of the specific GLP-1 drugs at issue—Ozempic and Wegovy. It was reasonable for the FDA to rely on data that was more timely and more pertinent to the relevant market.[64]

4

The Compounders argue that the FDA "improperly dismissed other evidence of a shortage," including (a) screenshots from particular pharmacies demonstrating Ozempic and Wegovy were out of stock or available in limited quantities, and (b) submissions from individuals demonstrating an inability to access Ozempic and Wegovy, including articles and blog posts.

The FDA's conclusion that the screenshots were not reliable evidence due to their "limitations" was not unreasonable. The FDA described

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[63] *See* Meg Tirrell, *The End of a Shortage of Popular Weight-Loss Drugs May Mean Many People Lose Access to Them*, CNN (Oct. 9, 2024), https://www.cnn.com/2024/10/09/health/tirzepatide-compounded-weight-loss-drugs/index.html ("[S]ome estimates put prescriptions for compounded versions as high as 20% of all prescriptions for the drugs.").

[64] *See Simpson v. Young*, 854 F.2d 1429, 1435 (D.C. Cir. 1988) (the FDA "need only state the main reasons for its decision and indicate that it has considered the most important objections").

screenshots it received from Hims & Hers Health, Inc. (Hims & Hers) that allegedly demonstrated Wegovy 0.5mg was unavailable to its "affiliated pharmacies" for purchase as of January 2025. But the FDA noted that the screenshots themselves were undated and did not include information about the duration of the unavailability. Other screenshots it received from Hims & Hers purportedly showed its "affiliate pharmacies continu[ing] to struggle to source" Wegovy as of December 2024, though, again, the screenshots themselves were undated.

The FDA also described screenshots it received from APC, FarmaKeio, and a law firm, some of which included date information. In the screenshots from APC, the date information included "updated as of," "anticipated recovery," and "expected availability in" the distribution center, with the latest date being December 2024. Screenshots from others included dates at the bottom of the computer screen, with the latest date also being in December 2024. Dates aside, however, the screenshots showed only some doses being unavailable, with others being available. Some screenshots contained only prices and unavailability of product without demonstrating with which product the prices and status were affiliated. The FDA additionally pointed out that some of the information did not disclose whether the pharmacy or compounder had access to order the product from a source other than the one in the screenshot.

In addition to the limitations the FDA recognized in the screenshots themselves, it provided logical reasons as to why a particular pharmacy's ordering portal as reflected in the screenshots may demonstrate product unavailability. The FDA explained that supply chain dynamics could lead to a specific pharmacy being unable to obtain Novo Nordisk's medications. There could be "distribution delays between locations, stocking and replenishment challenges with [Ozempic and Wegovy being] refrigerated products, ordering practices and timing, forecasting errors by the

retailer/pharmacy location (spikes and drops), financial incentive challenges at [pharmacies], and IT system issues." The FDA also explained that wholesalers may refuse to sell product to compounders who have not previously purchased a given medicine.

The Compounders argue that some screenshots from pharmacies ordering from wholesaler Cardinal Health included the statement that "supply is not 'sufficient to meet customer demand.'" Those screenshots, in full, stated: "Updated as of 11/11/2024[,] Manufacturer [Novo Nordisk] is allocating product to Cardinal Health. Until supply is sufficient to meet customer demand, Cardinal Health will allocate customers . . . ." Those screenshots are from November 2024, and the FDA did not declare the shortage over until February 2025. Evidence before the FDA demonstrated that wholesalers continuously increased their inventory from October to December 2024. It was not unreasonable for the FDA to conclude the shortage over in light of the record as a whole, despite this isolated screenshot evidence from particular pharmacies.

The Compounders emphasize that the FDA received many other submissions that individual patients were unable to access Ozempic and Wegovy, including reports from Hims & Hers, communications directly from individuals, articles, and blog posts. They contend that it does not "matter[] that these communications did not distinguish which GLP-1 drug or dose" the patients found unavailable since the FDA declared all tirzepatide and semaglutide products in shortage, criticizing the FDA for not considering the "information related together taken in totality."

The FDA's conclusion that this evidence could not outweigh Novo Nordisk's "more specific, reliable, comprehensive, and current" business data was not a clear error of judgment. The FDA cited multiple examples of this information in its decision and explained why it was less probative. One

example included the reports from Hims & Hers that the Compounders reference. These reports provided data regarding the number of people who conveyed to Hims & Hers an inability to access FDA-approved GLP-1 drugs through its online form—the same reports involved in *Eli Lilly*. As in *Eli Lilly*, the FDA explained the limitations of this evidence. We recognized those limitations in that decision, and we do not repeat them here.

Another example the FDA acknowledged was letters from individuals. It concluded this evidence was less probative because it contained "nearly identical communications that appear to be a form letter stating that, 'I'm not currently able to access the brand-name medications from Eli Lilly and Novo Nordisk.'" The FDA also acknowledged articles and blog posts that "contained personal accounts of inability to get a particular product at a particular time." But it stated, and the record reflects, that this information did "not include details of the reported individual experiences such as when the access issue occurred, what the access issue was, or" in some instances "which GLP-1 drug or dose was unavailable."

Furthermore, the FDA noted that it was hardly surprising that some individuals had trouble accessing Ozempic and Wegovy when those medicines were determined to be in shortage. It deduced that individuals reporting difficulty accessing the GLP-1 drugs could be explained by a variety of reasons. For instance, a pharmacy may have informed an individual complaining about access that the prescribed drug was not in stock. Or an individual's physician may have been unwilling to prescribe the drug to the individual. In either situation, the individual could have complained about access to the medicines regardless of whether the medications were actually in shortage. The FDA additionally noted that "practical dynamics" of the supply chain between Novo Nordisk and its customers, which is discussed above, could explain individual patient access.

The FDA's determination that this evidence was less probative than Novo Nordisk's business data was not unreasonable.

In sum, the FDA's Delisting Action was not arbitrary or capricious.

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