United States Court of Appeals
For the First Circuit

No. 20-1161

AKEBIA THERAPEUTICS, INC.,

Plaintiff, Appellant,

v.

ALEX MICHAEL AZAR, II, in his official capacity as Secretary of Health and Human Services, ET AL.,

Defendants, Appellees.

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

[Hon. Allison D. Burroughs, U.S. District Judge]

Before

Howard, Chief Judge,
Selya and Thompson, Circuit Judges.

Seth P. Waxman, with whom Bruce S. Manheim, Brian M. Boynton, Leon T. Kenworthy, Lindsey B. Silver, Wilmer Cutler Pickering Hale and Dorr LLP, and Nicole R. Hadas, were on brief, for appellant.

Jennifer B. Dickey, Deputy Associate Attorney General, Civil Division, U.S. Department of Justice, with whom Joseph H. Hunt, Assistant Attorney General, Andrew E. Lelling, United States Attorney, Abby C. Wright and Sarah E. Weiner, Attorneys, Appellate Staff, Robert P. Charrow, General Counsel, U.S. Department of Health and Human Services, Brenna E. Jenny, Deputy General Counsel, Janice L. Hoffman, Associate General Counsel, and Susan Maxson Lyons, Deputy Associate General Counsel for Litigation, were on brief, for appellees.

September 30, 2020

SELYA, **Circuit Judge**. In the modern world, the financial fortunes of a new prescription drug are often determined by how that drug is treated for reimbursement purposes by third parties. This appeal illustrates the point: in the underlying case, plaintiff-appellant Akebia Pharmaceuticals, Inc. (Akebia), sued a quartet of related federal defendants — the Secretary of the Department of Health and Human Services (HHS), the Administrator of the Centers for Medicare & Medicaid Services, and the entities that they lead[1] — complaining that CMS acted arbitrarily, capriciously, and contrary to law with respect to the reimbursement protocol for Akebia's new drug, Auryxia, when prescribed for treatment of iron deficiency anemia (IDA) in patients with chronic kidney disease (CKD). Akebia moved for a preliminary injunction, but the district court denied the motion. See Akebia Therapeutics, Inc. v. Azar, 443 F. Supp. 3d 219, 222 (D. Mass. 2020). After careful consideration, we affirm.

I. BACKGROUND

The federal Medicare statute provides health-care coverage for certain segments of the United States population, particularly individuals sixty-five years of age or older and

[1] We note two pertinent data points. First, both of the individual defendants are sued only in their official capacities. Second, the Centers for Medicare & Medicaid Services is the body within HHS responsible for generating the list of covered drugs that is at issue here. For ease in exposition, we refer to the defendants collectively as "CMS."

individuals with certain disabilities (regardless of age). See 42 U.S.C. § 1395c. Medicare is divided into several parts, each corresponding to a different dimension of the health-care landscape. This case revolves around Medicare Part D, which addresses prescription drug coverage for Medicare beneficiaries. See id. §§ 1395w-101 to -104.

As opposed to other types of Medicare coverage, through which the federal government pays health-care providers directly in a typical fee-for-service arrangement, Medicare Part D involves a contractual relationship with private insurance companies known as "sponsors." See id. § 1395w-112. Medicare beneficiaries select their preferred sponsor and benefits package and pay a monthly premium to the chosen sponsor. In turn, the sponsor receives reimbursement from the Medicare program for the cost of covered drugs.

As a default, Part D requires sponsors to provide Medicare beneficiaries access to all covered Part D drugs, subject to various exclusions. See id. § 1395w-111(e)(2)(A); see also id. § 1395w-102(a)(1)(A); id. § 1395w-102(b). A covered Part D drug is a drug dispensed by means of a prescription that the federal Food and Drug Administration (FDA) has approved as safe and effective. See id. § 1395w-102(e)(1)(A). In enacting Part D, Congress specified several categories of drugs that CMS may exclude

from coverage. See id. § 1395w-102(e)(2) (cross-referencing id. § 1396r-8(d)(2)).

The battleground in this case is a category of excluded drugs encompassing "[p]rescription vitamins and mineral products, except prenatal vitamins and fluoride preparations." Id. § 1396r-8(d)(2)(E). At the center of the dispute is the scope of this category, specifically, whether or not Auryxia, when prescribed for treatment of IDA in patients with CKD, constitutes a "mineral product" that CMS may properly exclude from coverage. Though this dispute is essentially legal in nature, it lends perspective both to sketch the factual underpinnings of Akebia's challenge and to rehearse the travel of the case.

In September of 2014, the FDA approved Auryxia for the treatment of hyperphosphatemia (elevated phosphate levels in the blood), a condition commonly associated with CKD, for patients who are receiving dialysis. Over three years later (in November of 2017), the FDA approved Auryxia for a second use: the treatment of IDA in patients with CKD who are not on dialysis. Akebia, which now owns Auryxia,[2] describes the drug as a ferric citrate coordination complex that differs from traditional iron supplements in that it facilitates iron transport to the blood rather than simply replacing missing iron. This distinction is

[2] In December of 2018, Akebia purchased Keryx Biopharmaceuticals, which had developed Auryxia.

salient, Akebia insists, because Auryxia can be used to treat patients who have sufficient iron stores but have difficulty transporting the iron to the blood in order to create red blood cells. Seen in this light, Auryxia offers an alternative to intravenous or oral iron supplements in situations in which such traditional iron supplements are ineffective for patients who have sufficient iron in their bodies but suffer from inadequate iron transportation to the blood.

Although Auryxia initially was covered under Part D for both of its permitted uses, CMS e-mailed sponsors in September of 2018, informing them that CMS had decided to exclude Auryxia from coverage when used to treat IDA in patients with CKD who are not on dialysis. CMS's e-mail stated that "[c]onsistent with other iron products, ferric citrate was removed" from the list of drugs covered under Part D. Following this guidance, Medicare sponsors thereafter refused to cover Auryxia when prescribed to treat IDA.

Inheriting the existing state of Medicare coverage in December of 2018, see supra note 2, Akebia made repeated efforts to extract information from CMS about the coverage determination and to persuade CMS to revisit it. These efforts included outreach to CMS, in-person meetings with CMS officials, and a formal legal memorandum submitted to both HHS's General Counsel and CMS's Chief Legal Officer. Akebia's campaign proved unavailing: on October

4, 2019, CMS affirmed its coverage determination, making clear that it would not revisit its position.

Within a matter of weeks, Akebia repaired to the federal district court. Its complaint alleged that CMS, in denying full Part D coverage of Auryxia, violated the relevant portions of the Medicare statute by improperly classifying Auryxia as a mineral product and excluding it from coverage. The complaint prayed that the district court set aside CMS's coverage determination as unlawful under the Administrative Procedure Act (APA), see 5 U.S.C. § 706(2)(A), and restore full coverage for Auryxia. Shortly thereafter, Akebia moved for a preliminary injunction, seeking to press "pause" on the coverage determination until CMS's interpretation could be fully litigated. Among other things, Akebia claimed that it was likely to succeed on the merits of its suit because CMS's interpretation of the Medicare statute was antithetic to the statutory text; because CMS had acted arbitrarily and capriciously by covering Auryxia for treatment of hyperphosphatemia but excluding it for treatment of IDA; and because CMS had compounded its arbitrary and capricious actions by reaching a coverage determination at odds with past CMS decisions. Following a hearing, the district court reserved decision and subsequently issued a thoughtful rescript in which it concluded that Akebia had failed to show a likelihood of success on the merits of its claims. See Akebia, 443 F. Supp. 3d at 222. After

making findings with respect to the other elements of the preliminary injunction calculus, see id. at 230-231, it denied Akebia's motion for preliminary injunctive relief, see id. at 231. This interlocutory appeal ensued. See 28 U.S.C. § 1292(a).

II. ANALYSIS

Our analysis proceeds in three segments. As an hors d'oeuvre, we start with CMS's contention that this matter is not justiciable. Next, we proceed to the appetizer and limn the standard of review associated with preliminary injunctions. Finally, we turn to the main course: Akebia's asseveration that the district court abused its discretion in refusing to grant a preliminary injunction.

A. Justiciability.

In this venue, as in the court below, CMS argues that the dispute between the parties is not fit for judicial review. This argument rests on two pillars. First, CMS says that Akebia did not properly channel its grievances through the agency's internal appeals processes. See 42 U.S.C. § 1395ii (incorporating id. § 405(h)). Second, CMS says that its coverage determination e-mail does not constitute final agency action and, thus, is not ripe for judicial review under the APA. See 5 U.S.C. § 704.

With respect to the first of these claims, CMS posits that Akebia has flouted the internal appeals process by attempting an end run around the Medicare Appeals Council (through which all

coverage disputes arising under the Medicare statute must be channeled). See Shalala v. Illinois Council on Long Term Care, Inc., 529 U.S. 1, 13 (2000). In response, Akebia brands this review process as inapposite, complaining that only Medicare beneficiaries — not drug manufacturers — have standing to bring administrative appeals to the Medicare Appeals Council. See 42 U.S.C. § 1395w-104(h)(1). So, Akebia's thesis runs, it should be excused from compliance with the existing review structure because that structure affords "no review at all" for its grievances. Shalala, 529 U.S. at 17.

Akebia's response strikes a nerve: CMS concedes that there is no intra-agency mechanism through which drug manufacturers may challenge coverage determinations for Medicare Part D. But CMS suggests that this is Akebia's tough luck, and CMS would leave Akebia high and dry, forcing Akebia to rely on individual beneficiaries to challenge the contested coverage determination to Akebia's behoof.

With respect to its second nonjusticiability claim, CMS suggests that the September 2018 e-mail (which contained the adverse coverage determination) was merely guidance to Medicare sponsors and, thus, not final agency action. Since a "final agency action" is a prerequisite to judicial review under the APA, 5 U.S.C. § 704, CMS submits that a reviewable Part D coverage determination may only be made by the Medicare Appeals Council.

Akebia demurs. The September 2018 e-mail, it says, satisfies the requirements for final agency action because it is a decision that marks the consummation of CMS's decisionmaking process (rather than a tentative decision) and is plainly a decision from which legal consequences flow. See Bennett v. Spear, 520 U.S. 154, 177-178 (1997). In this regard, Akebia notes both the apparent finality of CMS's coverage determination and the fact (which CMS does not deny) that Medicare sponsors are now expected to comply with this determination.

In appellate review, as in life, discretion is sometimes the better part of valor. The parties' arguments weave a jurisdictional riddle, which is both intricate and difficult to resolve. We are, however, steadfast in our belief that "courts should not rush to decide unsettled issues when the exigencies of a particular case do not require such definitive measures." Privitera v. Curran (In re Curran), 855 F.3d 19, 22 (1st Cir. 2017). So it is here.

To decide this appeal, it is not necessary for us to determine either whether Akebia has exhausted its intra-agency remedies or whether the CMS e-mail constituted final agency action. Although hypothetical jurisdiction is generally disfavored, see Steel Co. v. Citizens for a Better Env't, 523 U.S. 83, 94-95 (1998), such a barrier is insurmountable only when Article III jurisdiction is in issue, see First State Ins. Co. v. Nat'l Cas.

Co., 781 F.3d 7, 10 n.2 (1st Cir. 2015). The justiciability questions that CMS poses relate only to our statutory jurisdiction, not our Article III jurisdiction (which is not in doubt). Precedent teaches that where, as here, an appeal presents a question of statutory jurisdiction, that question need not be resolved if a decision on the merits will favor the party challenging the court's jurisdiction. See Caribbean Mgmt. Grp. v. Erikon LLC, 966 F.3d 35, 41 (1st Cir. 2020); First State, 781 F.3d at 10. Because this is such a case, we (like the court below, see Akebia, 443 F. Supp. 3d at 225), bypass the jurisdictional issue and go directly to the parties' dueling over the denial of preliminary injunctive relief.

B. Standard of Review.

When evaluating the denial of a preliminary injunction, our review is for abuse of discretion. See Ross-Simons of Warwick, Inc. v. Baccarat, Inc., 102 F.3d 12, 16 (1st Cir. 1996). We caution, though, that the abuse of discretion standard is not monolithic: under this rubric, we review the district court's answers to legal questions de novo, factual findings for clear error, and judgment calls with some deference to the district court's exercise of its discretion. See Corp. Techs., Inc. v. Harnett, 731 F.3d 6, 10 (1st Cir. 2013).

The framework for considering whether to grant or deny a preliminary injunction, properly enunciated by the court below,

has four elements. An inquiring court must gauge the movant's likelihood of success on the merits; must evaluate whether and to what extent the movant will suffer irreparable harm if injunctive relief is withheld; must calibrate the balance of hardships as between the parties; and must consider the effect, if any, that the issuance of an injunction (or the withholding of one) will have on the public interest. See Corp. Techs., 731 F.3d at 9; Ross-Simons, 102 F.3d at 15. In the precincts patrolled by the abuse of discretion standard, appellate review is respectful to the district court's weighing of these elements but falls well short of giving carte blanche to the district court's views. See Corp. Techs., 731 F.3d at 10.

We hasten to add that these four elements are not of equal prominence in the preliminary injunction calculus. The most important is whether the movant has demonstrated a likelihood of success on the merits – an element that we have described as the "sine qua non" of the preliminary injunction inquiry. Ryan v. ICE, __ F.3d __, __ (1st Cir. 2020) [No. 19-1838, slip op. at 11] (quoting New Comm Wireless Servs., Inc. v. SprintCom, Inc., 287 F.3d 1, 9 (1st Cir. 2002)). If the movant fails to demonstrate a likelihood of success on the merits, the remaining elements are of little consequence. See id.

Given the primacy of the likelihood-of-success element, that element forms the logical starting point for our analysis.

In this instance, the likelihood of Akebia's success depends largely on the force of its legal challenge to CMS's interpretation of the Medicare statute. Because we review the district court's answers to legal questions de novo, see Corp. Techs., 731 F.3d at 10, we find ourselves in essentially the same position as the district court with respect to this question. Thus, we effectively review CMS's interpretation of the Medicare statute through the lens of the standard articulated in the APA.[3] See Mass. ex rel. Div. of Marine Fisheries v. Daley, 170 F.3d 23, 28 (1st Cir. 1999). Under that standard, we will depart from the agency's conclusion only if its coverage determination proves to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A); see Doe v. Leavitt, 552 F.3d 75, 78 (1st Cir. 2009).

C. The Preliminary Injunction Inquiry.

Our construction of the preliminary injunction framework (see supra Part (II)(B)) makes pellucid that the sine qua non of a preliminary injunction is the movant's ability to show that it is likely to succeed on the merits of its claims. In examining

[3] Although review of administrative decisions under the APA often involves some degree of deference, see, e.g., Encino Motorcars, LLC v. Navarro, 136 S. Ct. 2117, 2124 (2016); Chevron U.S.A. Inc. v. NRDC, 467 U.S. 837, 844 (1984), this case falls outside the mine-run. Neither side has argued that CMS's September 2018 e-mail, which informed Medicare sponsors of its coverage determination regarding Auryxia, is entitled to any interpretive deference. We therefore afford it none.

the district court's denial of Akebia's motion for a preliminary injunction, we begin — and end — there.

As we already have indicated, Akebia's success or failure in this case turns principally on the soundness of CMS's interpretation of a statutory exclusion from Medicare Part D drug coverage. Consequently, our inquiry into the district court's holding that Akebia had failed to demonstrate a likelihood of success must commence with the relevant portion of the statutory text:

> The following drugs or classes of drugs, or their medical uses, may be excluded from coverage or otherwise restricted . . .
> (E) Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations.

42 U.S.C. §§ 1396r-8(d)(2)–(d)(2)(E). The threshold question involves whether Auryxia, when used to treat IDA in patients with CKD, is a "mineral product" within the purview of the statute and, thus, can be excluded from coverage under Part D.

In addressing this threshold question, we write on a pristine page. For aught that appears, this question is a question of first impression in the federal courts (except, of course, for the district court's decision), and CMS concedes that it has not formally promulgated a definition of "mineral products." Although we tackle this issue of statutory interpretation head on, we construe the statutory language only to determine Akebia's

likelihood of success on the merits. We do not purpose to resolve the issue definitively. See Ross-Simons, 102 F.3d at 16 (explaining that, at preliminary injunction stage, court of appeals "need not conclusively determine the merits of the underlying claims"); Narragansett Indian Tribe v. Guilbert, 934 F.2d 4, 6 (1st Cir. 1991) (cautioning that, at preliminary injunction stage, decisions "are to be understood as statements of probable outcomes" only).

Akebia chiefly contends that the word "mineral" must denote a substance that is naturally occurring and inorganic (devoid of carbon).[4] Relying on various dictionary definitions to this effect, Akebia insists that because Auryxia's active ingredient (ferric citrate) is man-made and not inorganic, Auryxia cannot come within the mineral products exclusion. CMS replies that the touchstone of the analysis is the total phrase "mineral products," which is necessarily inclusive of products that are manufactured for sale or are otherwise anthropogenic.

[4] For present purposes, we accept arguendo Akebia's proffered definition of the word "mineral," standing alone, as something "naturally occurring and inorganic." We note, though, that despite Akebia's litany of dictionary definitions, its proffered definition is not inevitable. The Supreme Court has warned that because the word "mineral" is used in many disparate contexts, dictionary definitions should generally be disfavored. See Watt v. W. Nuclear, Inc., 462 U.S. 36, 42-43 (1983). Against this backdrop, we are not prepared to discount entirely CMS's argument that Congress probably did not intend that "mineral," as used in the Medicare statute, should encompass all dictionary-captured coal, stone, or other earthly materials.

The court below found Akebia's definition of "mineral products" too narrow, ruling instead that Congress intended for "mineral products" to encapsulate man-made substances in addition to those found in the natural world. See Akebia, 443 F. Supp. 3d at 226. On this basis, the court concluded that CMS's decision to exclude Auryxia from coverage when used to treat IDA was not contrary to law. Id. We agree.

The text of the statute authorizes the exclusion of "mineral products" not just "minerals." To accept Akebia's isthmian definition, limited to just the word "mineral," would require us to ignore a critical aspect of the exclusion category: the word "products." Whenever feasible, courts ought to interpret statutory language in ways that avoid rendering specific words or phrases superfluous. See Gustafson v. Alloyd Co., 513 U.S. 561, 574 (1995); United States v. Walker, 665 F.3d 212, 225 (1st Cir. 2011). This principle has obvious relevance here: Congress easily could have used the word "mineral" alone, but instead chose to use the broader term "mineral products." The addition of the word "products" implies some kind of human modification to the mineral itself. See, e.g., Webster's Third New International Dictionary (1961) (defining "product" as "something produced by physical labor or intellectual effort; the result of work or thought"); Black's Law Dictionary (9th ed. 2009) (defining "product" as "[s]omething that is distributed commercially for use or

consumption and that is usu[ally] (1) tangible personal property, (2) the result of fabrication or processing, and (3) an item that has passed through a chain of commercial distribution before ultimate use or consumption."). If the statute only authorized CMS to exclude naturally occurring, inorganic substances (as Akebia suggests), the word "products" would serve no useful purpose.

In addition, the text of the statute as a whole strongly supports CMS's more expansive interpretation. The statute authorizes the exclusion of "[p]rescription vitamins and mineral products, except prenatal vitamins and fluoride preparations." 42 U.S.C. § 1396r-8(d)(2)(E). The fact that Congress explicitly exempted "fluoride preparations" elucidates the breadth of the mineral products exclusion. While fluoride itself is a naturally occurring substance that fits Akebia's proposed definition of "mineral," "fluoride preparation" necessarily denotes some kind of man-made process altering fluoride, the raw material. It follows, we think, that but for the explicit exemption, fluoride preparations — which themselves are not naturally occurring — would have been covered under the mineral products exclusion. And although we need not speculate as to why Congress decided to save fluoride preparations specifically from exclusion, that decision makes manifest that the term "mineral products" encompasses

manufactured products, like Auryxia, and not solely naturally occurring substances.

Akebia struggles mightily to parry this thrust. It says that the presence of "fluoride preparations" in the statute does not undermine its interpretation of "mineral products" because fluoride itself is a naturally occurring substance. In contrast, the active ingredient in Auryxia is, in Akebia's parlance, a "novel organic compound." The mere presence of a manufacturing process, Akebia muses, does not itself make something a mineral product, given that the active ingredient in Auryxia is not a mineral.

We are not moved by this proposed distinction. In our view, Congress's inclusion of "fluoride preparations" in the statute strikes at the heart of Akebia's contention that only naturally occurring substances can be properly excluded under the statute. Fluoride preparations are not naturally occurring substances, and the fact that Congress saved them from exclusion indicates to us that the mineral products exclusion necessarily encompasses non-naturally occurring substances. Any other reading elevates hope over reason.

Relatedly, Akebia argues that even if the mineral products exclusion covers certain man-made substances, a drug can be a mineral product and therefore eligible for exclusion only if its active ingredient is naturally occurring and inorganic, that is, a mineral. Because Auryxia's active ingredient is a "novel

organic compound" that is "synthetically produced," Akebia submits, it falls outside the compass of the exclusion. In support, Akebia tries to use CMS's words against it, noting that in its opposition to the preliminary injunction motion, CMS represented that the term "mineral products" includes a manufactured product that contains a mineral as an active ingredient.[5]

To be sure, we agree with Akebia's premise: parties may be bound by statements made in court filings. See, e.g., Harrington v. City of Nashua, 610 F.3d 24, 31 (1st Cir. 2010) (noting that such admissions must be "clear" in order to be binding); Schott Motorcycle Supply, Inc. v. Am. Honda Motor Co., 976 F.2d 58, 61 (1st Cir. 1992) (holding party bound by "clear and express statement" in its original and amended complaints). We disagree, however, with the conclusion that Akebia would have us draw in this case.

First and foremost, we do not read the statement as undercutting the position that CMS has taken. And even assuming, for argument's sake, that the active ingredient in Auryxia is a synthetically produced, organic compound that is not a mineral,

[5] CMS's actual language is more ambiguous than Akebia suggests. CMS's opposition stated that the mineral products exclusion "reasonably includes manufactured items containing a mineral as an active ingredient" even when the product is man-made.

the presence of such an active ingredient would not negate the fact that iron sits at the core of the drug's raison d'être. More importantly, Akebia's insistence that the active ingredient itself must be a mineral ignores the centrality of the word "products" in both the statutory language and in the excerpt from CMS's opposition to the preliminary injunction motion. As we already have explained, Congress clearly intended the term "mineral products" to encompass synthetic substances in addition to those found in nature. In context, then, Akebia's insistence that Auryxia cannot be a "mineral product" because its active ingredient is not a mineral is nothing short of magical thinking. The statute simply does not provide that the presence of a synthetic active ingredient, in and of itself, renders something not a mineral product and prohibits CMS from deploying the mineral products exclusion.

Akebia resists this conclusion, suggesting that it would result in an endless list of excluded drugs because any drug that contained even a smidgen of mineral could be excluded. But Akebia is whistling past the graveyard. CMS has not taken an interpretive stance that even remotely threatens so extreme an outcome. Its position is much more circumscribed: it will exclude such a drug only if it is used to treat a mineral deficiency. Although we do not purpose to resolve this interpretative question definitively at the preliminary injunction stage, see Ross-Simons, 102 F.3d at

16, we find that Akebia has not demonstrated a likelihood of success on its claim that CMS's interpretation of the mineral products exclusion is arbitrary, capricious, or otherwise contrary to law. See Leavitt, 552 F.3d at 78.

Ably represented, Akebia looses a barrage of other arguments. To begin, it observes that the FDA has approved Auryxia to treat two conditions associated with CKD: hyperphosphatemia and IDA. With respect to Part D coverage, though, CMS has excluded Auryxia only when used to treat IDA. From this medley of facts, Akebia argues that covering Auryxia for one use but excluding it for the other is arbitrary and capricious. Embedded in this argument are two distinct but imbricated propositions. First, Akebia submits that the statutory language does not support any use-based distinctions at all. Second, it submits that even if some use-based distinctions are permissible, Auryxia does not actually treat a "mineral deficiency" that would fit within the Agency's use-based paradigm. We examine these propositions separately.

Whether the Medicare statute authorizes CMS to exclude from coverage certain uses of a drug but not others is a question of law that we review de novo. See Corp. Techs., 731 F.3d at 10. Here, the introductory language to the relevant statutory section provides that "[t]he following drugs or classes of drugs, or their medical uses, may be excluded from coverage or otherwise

restricted." 42 U.S.C. § 1396r-8(d)(2). The exclusion categories (including the mineral products exclusion) are then enumerated. Some of the exclusion categories list broad classes of drugs, such as "[p]rescription vitamins and mineral products." Id. § 1396r-8(d)(2)(E). Other exclusion categories focus specifically on particular uses that may be excluded, such as "[a]gents when used for cosmetic purposes or hair growth." Id. § 1396r-8(d)(2)(C).

If a statute's plain meaning supplies a plausible interpretation, then that interpretation ordinarily wins the day. See United States v. Gordon, 875 F.3d 26, 33 (1st Cir. 2017). In this instance, Congress spelled out the powers that it conferred upon CMS quite clearly: CMS may exclude from coverage "[t]he following drugs or classes of drugs, or their medical uses." 42 U.S.C. § 1396r-8(d)(2) (emphasis supplied). By excluding Auryxia (a mineral product, see text supra) from coverage only for a particular medical use, CMS took exactly the sort of action that Congress authorized it to take. In other words, CMS acted well within the encincture of the discretion afforded to it by the statute.

Akebia's contrary argument, which posits that the mineral products exclusion only authorizes the Agency to exclude mineral products in their entirety, is unconvincing. This argument suggests that because some exclusion categories begin with the phrase "[a]gents when used for," drugs in all other exclusion

categories may only be excluded based on their composition, not their medical uses. Such a suggestion, though, is not only belied by the plain language of the statute but also would render the statutory phrase "or their medical uses" nugatory. That sort of construction is to be avoided. See Gustafson, 513 U.S. at 574; see also Walker, 665 F.3d at 225.

Here, moreover, if the entire universe of CMS's exclusion options were listed alongside the exclusion categories themselves, there would have been no earthly reason for Congress to have included the phrase "or their medical uses" in the statute. Put another way, if Akebia's interpretation prevailed, the words "or their medical uses" could be deleted and the statute's meaning would be unchanged. Like the district court, see Akebia, 443 F. Supp. 3d at 230, we refuse to place our imprimatur on so fanciful an exercise in statutory interpretation.

Nor does the fact that certain exclusion categories begin with "[a]gents when used for" alter our conclusion. As employed in the statute, nothing about that phrase implies that other categories may only be excluded in an all-or-nothing manner, premised on chemical composition. It is both plausible and consistent with the statutory text to conclude — as we do — that Congress wished to provide CMS with somewhat limited authority to exclude drugs in certain categories while allowing CMS wider latitude with respect to other categories.

To say more about this line of argument would be to paint the lily. We conclude, without serious question, that the plain language of the statute authorizes use-based distinctions for Part D coverage determinations. We also conclude that the use-based distinction that CMS has made regarding Auryxia comes under the umbrella of this authority. Akebia's contrary claims, therefore, cannot undergird a showing of likelihood of success on the merits.

This brings us to Akebia's claim that even if use-based distinctions are permissible under the statute, Auryxia does not come within the contours of the excludable medical use that CMS articulated before the district court. In its opposition to the preliminary injunction motion, CMS asserted that the excludable use for mineral products is for "manufactured products prescribed for conditions arising from a mineral deficiency." It also asserted that this interpretation was consistent with its September 2018 e-mail to Medicare sponsors. Building on a foundation constructed out of these assertions, Akebia notes that Auryxia is often prescribed to patients that have functional iron deficiency — a condition in which patients have sufficient iron stores in their bodies but have difficulty using that iron to create red blood cells.

As Akebia sees it, functional iron deficiency contrasts with absolute iron deficiency (a condition in which the body simply does not have enough iron). Auryxia effectively helps patients

with functional iron deficiency transport the iron they already have to the correct place (by making the iron more soluble) so that the body can create red blood cells; it does not replace the iron altogether. This unique feature of Auryxia, Akebia maintains, means that Auryxia does not treat an iron deficiency but, rather, treats an iron transport problem.

Akebia tells us that this distinction is of decretory significance because Auryxia is often prescribed to patients with functional iron deficiency — patients who do not respond well to traditional iron supplements because they have all the iron they need. Understood in this way, Auryxia does not treat an iron deficiency but treats an iron transport problem and, thus, cannot (Akebia says) be excluded under the statute. To support this understanding, Akebia relies on statements from a variety of medical and scientific professionals.

We do not gainsay that this technical distinction is significant. For instance, it quite probably played a meaningful role in Auryxia's patent applications. But it does not tell the whole story: other factors swing the interpretive pendulum back in CMS's favor. The most prominent of these factors is that Auryxia is prescribed to treat IDA. IDA is a diagnosis indicating that the body lacks the iron required for normal physiological processes, even if the individual has adequate iron stores elsewhere in the body.

There is more. Notwithstanding Akebia's efforts to differentiate Auryxia from traditional intravenous and oral iron supplements by focusing on the part that Auryxia plays in iron transport, the label required by the FDA describes Auryxia as an "iron replacement product" — a term that clearly implies that something is being replaced. This implication goes hand in hand with the notion that — in contrast to treatment for hyperphosphatemia, in which Auryxia is used like a paper towel to soak up excess phosphates — the principal objective in IDA treatment is to facilitate iron absorption, with an eye toward ameliorating otherwise deficient iron levels in the blood. Auryxia's underlying patent filings focus on the solubility of the compound, buttressing the idea that the goal is to restore (or at least improve) the patient's iron levels.

At bottom, the parties are arguing about whether Auryxia, when prescribed for patients who have trouble using stored iron to create red blood cells, should be regarded as treating a mineral deficiency. This is a close question, but it is a question of fact. The district court treated it as such and found that Auryxia, when prescribed to patients with IDA, is a mineral product

used to treat an iron deficiency.[6] See Akebia, 443 F. Supp. 3d at 229.

Under the abuse of discretion standard, we review such factual findings only for clear error. See Corp. Techs., 731 F.3d at 10. The particular factual finding under review results from a plausible view of the evidence and is not clearly erroneous. The FDA's characterization of Auryxia as an iron replacement product and the fact that Auryxia is prescribed to treat IDA both lend credence to the district court's conclusion. See Cumpiano v. Banco Santander P.R., 902 F.2d 148, 152 (1st Cir. 1990) (explaining that, on clear error review, we "ought not to upset findings of fact or conclusions drawn therefrom unless, on the whole of the record, we form a strong, unyielding belief that a mistake has been made.") (citing, inter alia, United States v. U.S. Gypsum Co., 333 U.S. 364, 395 (1948)); cf. id. ("Where there are two permissible views of the evidence, the factfinder's choice between them cannot be clearly erroneous.") (quoting Anderson v. City of Bessemer City, 470 U.S. 564, 574 (1985)). It follows that, at this stage of the litigation, Akebia's claim of error fails.

Akebia makes a last-ditch effort to bell the cat. It contends that CMS's decision to exclude Auryxia from Part D

[6] We recognize that, at the preliminary injunction stage, this finding is merely a predicted outcome, subject to reexamination at a trial on the merits. See Ross-Simons, 102 F.3d at 16.

coverage for some uses but not for others is arbitrary and capricious because that decision is inconsistent with CMS's treatment of analogous drugs. To support this contention, Akebia points to CMS's prior decisions concerning several non-iron products, including vitamin D products and electrolytes.

The fatal flaw in this contention is that it rests on a claim that CMS cannot make coverage determinations based on use — a claim that we already have rejected. See text supra. Given our acknowledgment of CMS's authority to employ a use-based approach, little more need be said. We add only that, in this context, the usual reason for finding an agency's decision arbitrary and capricious is the existence of "a deviation from its own prior precedents without sufficient explanation or reasoning." Good Samaritan Med. Ctr. v. NLRB, 858 F.3d 617, 629 (1st Cir. 2017). To succeed on such a claim, Akebia would need to demonstrate that CMS departed from either norms previously established or its customary decisional rules when it decided to exclude Auryxia from coverage. See Int'l Jr. Coll. of Bus. and Tech., Inc. v. Duncan, 802 F.3d 99, 112-113 (1st Cir. 2015); Shaw's Supermarkets, Inc. v. NLRB, 884 F.2d 34, 36-37 (1st Cir. 1989). Here, however, CMS did not deviate in any meaningful way from its own prior coverage determinations: its use-based approach to Auryxia is consistent not only with its treatment of other iron replacement products but

also with its treatment of the other products that Akebia mentions. We explain briefly.

To begin, Akebia's argumentation is under-inclusive. In alleging that CMS acted inconsistently, Akebia's comparisons conspicuously omit any serious discussion of CMS's classification of other drugs used for the treatment of iron deficiency. Iron supplements are Auryxia's closest analog, and CMS has regularly excluded from coverage under Part D other iron products used to treat IDA. See Akebia, 443 F. Supp. 3d at 227. Intravenous and injectable iron drugs containing synthetic substances (such as iron dextran, iron sucrose, and sodium ferric gluconate) are uniformly excluded from Part D coverage when used to treat IDA. So, too, polysaccharide iron complex, an orally-ingested iron replacement product, is excluded from Part D coverage.

Apparently aware that it cannot win this battle, Akebia seeks to make other (and less appropriate) comparisons. To this end, it attempts to contrast CMS's decision regarding Auryxia with CMS's coverage determinations for vitamin D products, synthetic compounds combined with citric acid such as lithium salts, niacin-based products, and electrolytes. These comparisons, though, are flying under a false flag. The fundamental takeaway from CMS's prior coverage decisions regarding the products singled out by Akebia is that each decision was predicated on the use of the particular product. Some examples suffice to make the point:

- CMS decided to exclude certain vitamin D products, known as "nutritional vitamin D," from Part D coverage because such products directly treat a vitamin D deficiency. On the contrary, CMS decided to cover other vitamin D products, known generically as "active vitamin D," under Part D because they treat hyperparathyroidism by inhibiting the parathyroid glands' secretion of certain hormones. Nothing about these decisions is inconsistent with CMS's treatment of Auryxia.
- CMS decided to cover niacin-based products, which contain vitamin B3 for treatment of dyslipidemia (abnormal lipid counts in the blood) rather than for treatment of vitamin B3 deficiency. Nothing about this decision is inconsistent with CMS's treatment of Auryxia.
- CMS decided to cover products composed of synthetic mineral compounds combined with citric acid, including lithium salts, when used to treat conditions other than mineral deficiencies (such as psychiatric disorders). Nothing about this decision is inconsistent with CMS's treatment of Auryxia.

- CMS decided to cover certain electrolytes under Part D, even when used as replacement products (but only when used to replace electrolytes, not non-electrolyte minerals). To the extent that a product has both electrolyte and non-electrolyte mineral components, the product is not covered if used to replace the non-electrolyte mineral.[7] Nothing about this decision is inconsistent with CMS's treatment of Auryxia.

Over and above these examples, we offer one last observation. As a general matter, the vitamin and mineral products category is broad enough that it would be odd to require CMS to treat all products that potentially fall within it exactly the same. The text of the statute gives us no reason to think that Congress intended to impose so curious a regime. See, e.g., Shaw's Supermarkets, 884 F.2d at 41 (holding that agencies need not "microscopically examin[e] prior cases" and that prior cases are not "straitjacket[s], inhibiting experimentation or change").

[7] Akebia argues that because electrolytes are a subset of minerals, CMS cannot legitimately cover electrolyte but not mineral replacement products. At this moment, however, challenges to CMS's coverage decisions regarding electrolytes are not before us. The key query is whether CMS's decision regarding Auryxia was a significant departure from its prior coverage determinations, see Shaw's Supermarkets, 884 F.2d at 36; and at this stage, we agree with the district court that it was not, see Akebia, 443 F. Supp. 3d at 229.

That ends this aspect of the matter. Although an agency must be sufficiently consistent in its decisionmaking to avoid arbitrary and capricious outcomes, it need not always be precise to the point of pedantry. See Davila-Bardales v. INS, 27 F.3d 1, 5 (1st Cir. 1994) (recognizing that "agencies retain a substantial measure of freedom to refine, reformulate, and even reverse their precedents in the light of new insights and changed circumstances"). The basic rule is that an agency cannot significantly depart from its own prior precedent without adequately explaining its rationale. See Shaw's Supermarkets, 884 F.2d at 36. There was no such departure here: the record reflects that CMS acted in reasonable conformity with its past decisions regarding analogous products. Because CMS treated its coverage of Auryxia consistently with its past decisions concerning iron products and other drugs falling under the vitamins and mineral products exclusion, the district court did not abuse its discretion in holding that CMS's treatment of Auryxia was neither arbitrary nor capricious.

III. CONCLUSION

We need go no further. Inasmuch as we find neither cognizable error nor abuse of discretion in the district court's holding that Akebia failed to carry its burden of showing that it is likely to succeed on the merits of its claims, we need not address the other elements of the preliminary injunction

framework. See Wine & Spirits Retailers, Inc. v. Rhode Island, 418 F.3d 36, 54 (1st Cir. 2005). After all, we have made it luminously clear that likelihood of success is the "sine qua non" of the preliminary injunction inquiry. Ryan, __ F.3d at __ [slip op. at 11] (quoting New Comm Wireless Servs., 287 F.3d at 9).

Affirmed.