23-7246

United States Court of Appeals
For the Second Circuit

ASCENT PHARMACEUTICALS, INC.,

Petitioner,

v.

UNITED STATES DRUG ENFORCEMENT ADMINISTRATION

Respondent,

On Petition for Review of an Order of the U.S. Drug Enforcement Administration

EMERGENCY MOTION FOR MANDATORY PRELIMINARY INJUNCTIVE RELIEF

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INTRODUCTION

More than six million children in the United States have ADHD,[1] but they cannot get their medications. The U.S. is short by about *one billion dosage units*.[2] In the midst of this crisis, the Drug Enforcement Administration ("DEA") has effectively shut down one of the nation's largest manufacturers of generic ADHD medications. This case demands emergency relief.

Ascent Pharmaceuticals, Inc. ("Ascent") has manufactured about 20% of the nationwide supply of generic ADHD medications. Founded in 2011, it is one of the nation's few minority-owned drug companies. It has operated for 12 years without any regulatory violations. In mid-2022, Ascent applied to DEA for its yearly quota of raw materials for 2023. After bumbling about for 18 months reviewing Ascent's business records, DEA denied the quota applications on Friday, September 29, 2023 (the "Quota Denial").

Why? That is an excellent question—one DEA never answered in its final decision. The only justification DEA offered is that it "lacked confidence" in Ascent's recordkeeping. The Quota Denial nowhere explains the basis for DEA's alleged confidence gap. If that detail resides in the administrative complaint served

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[1] ADHD is attention deficit hyperactivity disorder, which, if left untreated, leaves children at increased risk for anxiety, depression, sleep disorders, substance abuse, and suicide. *See* Walden Decl. Ex. 1, at 1.

[2] *See* Walden Decl. Ex. 2.

alongside the Quota Denial, DEA should be embarrassed: the errors in it reveal a fundamental inaptitude with DEA's own recordkeeping requirements.[3]

This case highlights the perils of a hapless administrative agency, which (ironically) acknowledged the scarcity of ADHD medications on the very day it effectively sought to shutter Ascent,[4] a company with a time-proven capability of quickly getting medicine to children in need. Ascent and patients have been victimized by DEA's incompetence, having rendered an arbitrary, capricious, and unsubstantiated quota denial based on erroneous conclusions. DEA's errors cannot credibly be denied. Yet, when presented with these errors, DEA stubbornly doubled down, as described below, ignoring the needs of ADHD patients. Now, a vibrant company, making critically important medications for kids, is on the precipice of extinction. This Court should set DEA straight and permit Ascent to continue making vital ADHD medicines by directing DEA to approve Ascent's requested quotas.

[3] Sarah Pechnick, a 13-year veteran of DEA and expert on its regulatory scheme, describes DEA's actions as "without precedent" and "particularly problematic" in light of the current ADHD crisis. Pechnick Decl ¶ 25.

[4] Less than a half-hour after denying Ascent's Quota Applications on September 29th, DEA raised the nationwide aggregate production quota for methylphenidate, a key component of most ADHD medications. *See* Walden Decl. Ex. 3, at 1-3.

I. BACKGROUND

The pertinent facts are simple. DEA delayed action on Ascent's request for controlled-substance procurement quotas for 2023, including for raw materials used to make ADHD drugs. It delayed action while it conducted an 18-month review of Ascent's business records. Ascent timely produced records and provided answers and documents to address DEA's concerns. When DEA would not relent and award the quotas, Ascent sued in federal district court to force a decision. Only then did DEA issue the Quota Denial. In the meantime, the nation was suffering from a severe shortage of ADHD medications. Ascent was unable to procure materials for production due to DEA's inaction. Sabbella Decl. ¶ 11. In August 2023, it produced a little more than 100,000 doses of controlled substances, while in March 2022 alone it produced 108 million. *Id.* ¶ 10. A more detailed explanation follows.

A. The Regulatory Landscape

The Controlled Substances Act ("CSA") requires DEA to annually determine the total manufacturing quantity of each controlled substance on Schedule I and Schedule II. *See* 21 U.S.C. §826(a). Procurement quotas and individual manufacturing quotas are then derived from the aggregate production quotas for each drug. *See* 21 C.F.R. §§ 1303.11-1303.13.

As a controlled substance manufacturer, Ascent is subject to DEA's rules and regulations. Pursuant to statute, drug manufacturers submit yearly applications for

procurement quotas for each controlled substance for the following year. 21 C.F.R. § 1303.12(b). DEA must respond to qualified applicants on or before July 1 of the year of the application, which addresses quotas for the following year. *See* 21 C.F.R. § 1303.12(c). Thus, applications to obtain quotas for calendar year 2023 were due in April 2022, and DEA was required to grant, modify, or reject those applications by July 1, 2022.

B. Ascent's Quota Applications

In mid-2022, Ascent submitted applications seeking quotas to procure raw material for 11 controlled substances (the "Quota Applications").[5] *See* Jayaraman Decl. Exs. 1-11. Among them were requests for quotas for five drugs—Dexmethylphenidate, Methylphenidate, Lisdexamfetamine, D,L Amphetamine, and D-Amphetamine (the "ADHD Raw Materials")—used to make eight different ADHD medications, including generic versions of Adderall, Concerta, Methylin, Ritalin, and Vyvanse. Jayaraman Decl. ¶¶ 11-16. Only a small handful of companies manufacture the generic versions of these drugs in the U.S. Sabbella Decl. ¶ 11.

[5] Some of Ascent's applications were submitted late, but DEA's normal practice is to respond to applications submitted after the deadline and generally does not find untimeliness disqualifying. Pechnick Decl. ¶ 14. DEA has never cited untimeliness to Ascent as a reason for its delay. Jayaraman Decl. ¶¶ 23-26.

C. DEA Pours Over Ascent's Records for 18 Months

Since May 3, 2022, DEA began a regulatory inspection of Ascent. These reviews vastly exceeded the scope of DEA's typical review of quota applications.[6] *See* Pechnick Decl. ¶¶ 17-18. Ascent cooperated fully, often producing thousands of documents within a few business days of the requests. Jayaraman Decl. ¶¶ 20, 21.

D. The Scarcity of ADHD Drugs Gets Worse

In the meantime, various stakeholders—congresspeople, government agencies, and distributors—implored Ascent to accelerate its production of ADHD medications. Concerned about scarcity, Ascent beseeched DEA to grant its Quota Applications. Ascent asked for calls or meetings to address any DEA concerns numerous times, but DEA never responded. Jayaraman Decl. ¶¶ 24-25. Instead, DEA demanded tens of thousands of business records from Ascent. Jayaraman Decl. ¶ 21. Ascent fully complied, making at least 5 document productions. *Id.* ¶ at 21, n. 1.

Meanwhile, the acute shortage of ADHD medications worsened. Between July 18, 2023, and September 22, 2023, the U.S. Food and Drug Administration

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[6] These inquiries typically concern missing information on the application form, current or previously approved quota, reconciliation of data on the application with the data in DEA's possession, and similar ministerial questions. Pechnick Decl. ¶ 17.

("FDA") contacted Ascent asking whether it had additional supply of ADHD medications. Jayaraman Decl. ¶¶ 27-29. The Offices of Senators Sheldon Whitehouse and Ron Wyden also reached out to Ascent directly to inquire what Ascent could do about the shortage. *Id*. at ¶ 30. Each time, Ascent was forced to reply that its hands were tied because of DEA's failure to respond to its Quota Applications. *Id.*

E. Recordkeeping Concerns Debunked

Finally, on November 11, 2022 DEA revealed its concerns: it claimed Ascent had problems with its recordkeeping. None of these purported issues affected quality control of Ascent's manufacturing or suggested the possibility of diversion of controlled substances. Nevertheless, perplexed by this conclusion, Ascent hired a nationally renowned expert, Krista Tongring, to conduct a thorough review of its compliance and recordkeeping practices. Tongring Decl. ¶ 11-12. She concluded that Ascent's records complied with DEA laws and regulations. *Id.* ¶ 13. She promptly communicated her findings to DEA on September 15, 2023. True to form, DEA did not respond. *Id.* ¶ 14.

F. Without Options, Ascent Files Suit and DEA Retaliates

By September 2023, DEA had still not decided the Quota Applications. As a result, Ascent ran out of ADHD Raw Materials and stopped producing most ADHD medications. Jayaraman Decl. ¶ 34. Its business suffered as a result, and it lost more

than 100 employees. Sabella Decl. ¶ 13. Without any options, it filed suit in the Eastern District of New York on September 27, 2023, seeking to compel DEA to decide the Quota Applications.[7]

DEA's retaliation was immediate. The next day, on September 28, 2023, DEA served Ascent with an Order to Show Cause ("OTSC"), which sought to rescind Ascent's DEA registrations based on erroneous and exaggerated allegations of recordkeeping violations. Jayaraman Decl. Ex. 12. The following day, DEA issued a decision denying the Quota Applications in their entirety. Jayaraman Decl. Ex. 13. The Quota Denial stated:

> In considering Ascent's requests for quota, DEA's Diversion Control Division received records pursuant to DEA's authority under 21 CFR 1303.12(b) to request additional information that "may be helpful in detecting or preventing diversion." After reviewing these records, **DEA lacks confidence in the data provided by Ascent in its quota requests**, a relevant "other factor" in reaching quota determinations pursuant to 21 U.S.C. 826(c).

Id. (emphasis added). DEA gave no other explanation. The letter did not mention any right or method to appeal the decision.[8]

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[7] *See Ascent Pharmaceuticals, Inc. v. U.S. Drug Enforcement Administration*, No. 2:23-cv-07211 (E.D.N.Y. Sep. 27, 2023). Following receipt of the Quota Denial, Ascent voluntarily withdrew the Complaint on October 2, 2023.

[8] On September 30, 2023, Ascent requested that DEA confirm the Quota Denial was a final decision by the Administrator and that no administrative appeals were available. Again, DEA failed to respond. *See* Walden Decl. ¶ 3.

II. ARGUMENT

To obtain a mandatory preliminary injunction, a movant must make a "strong showing" of irreparable harm and a "clear or substantial" showing of likelihood of success on the merits, in addition to showing that the public interest and a balance of equities are in its favor. *Yang v. Kosinski*, 960 F.3d 119, 127–28 (2d Cir. 2020). We address each factor below.

A. Irreparable Harm is Undeniable

Irreparable harm is "the single most important prerequisite" for a preliminary injunction. *Olson v. Wing*, 281 F. Supp. 2d 476, 486 (E.D.N.Y. 2003), *aff'd*, 66 F. App'x 275 (2d Cir. 2003) (citations omitted). A movant carries its burden by showing "a continuing wrong which cannot be adequately redressed by final relief on the merits" for which "money damages cannot provide adequate compensation." *New York Pathological & X-Ray Lab'ys, Inc. v. Immigr. & Naturalization Serv.,* 523 F.2d 79, 81 (2d Cir. 1975) (citation omitted). In evaluating the movant's case, a court can consider harm to the parties and to the public. *Long Island R.Co. v. Int'l Ass'n of Machinists*, 874 F.2d 901, 910 (2d Cir. 1989). Here, both forms of harm are clear.

1. **Harm to public**. Irreparable harm to the public here is manifest. Ascent made about 20% of generic ADHD drugs before DEA's war of attrition. Sabella Decl. ¶ 11. All the while, the nation has been plagued with a critical

shortage of ADHD medications. Across the country, patients—including parents of diagnosed children— have been unable to fill prescriptions. *See* Walden Decl. Ex. 4, at 1-2. The scarcity of brand-name and generic-equivalent prescriptions has been linked to depression, withdrawal, and declines in learning and self-esteem. Walden Decl. Ex. 5, at 3-4. Deservedly, DEA has been widely criticized for failing to sufficiently address the problem, and there have been calls by Congress and FDA to increase supply. *See, e.g.,* Walden Decl. Ex. 6, at 1.

Meanwhile, Ascent has been forced to the sidelines despite its pleading with DEA to respond to the Quota Applications. This has not been lost on others. FDA contacted Ascent multiple times, including as recently as September 2023, asking if Ascent had additional supply of certain ADHD medications. Jayaraman Decl. ¶ ¶ 27-29. The Offices of two U.S. senators similarly sought Ascent's help with the shortage. *Id.* ¶ 30. Each time, Ascent replied that its hands were tied by DEA's inaction. *Id.* Now, DEA has severed those hands by arbitrarily denying the Quota Applications based on alleged recordkeeping problems—some which are wholly "erroneous," and others "common and correctable," but none of which normally play a role in quota determinations. Tongring Decl. ¶ 32; Pechnick Decl. ¶ 26.

Courts have long recognized that harm to patient health can support a finding of irreparable harm. *See, e.g., Olson*, 281 F. Supp. 2d at 487 ("[c]hronically-ill [patients] . . . deemed ineligible for [medical] benefits surely face the threat of

irreparable harm"); *John E. Andrus Mem'l, Inc. v. Daines*, 600 F. Supp. 2d 563, 572 (S.D.N.Y. 2009) (irreparable harm to nursing home patients forced to relocate and suffering from potential health consequences if home closed).

For example, in *Leddy v. Becerra*, the Department of Health and Human Services ("HHS") issued an administrative order prohibiting a doctor from participating in federal health programs after he was convicted for obstructing a Medicare audit. 617 F. Supp. 3d 116, 118 (E.D.N.Y. 2022). The order would likely have been "the death knell for his medical practice," which was "a critical resource for 5,000 patients." *Id.* The court granted the plaintiff a temporary restraining order, explaining that the "harm to the plaintiff and his practice, harm to his patients, harm to the community" would be irreparable. *Id.* at 122. It also found that immediate relief was warranted because the order "would likely irrevocably doom the medical practice before reasoned review could occur." *Id.*

Similarly, in *Strouchler v. Shah*, the court granted a preliminary injunction enjoining the State Department of Health from reducing and, in some cases, terminating 24-hour home care services for disabled patients. 891 F. Supp. 2d 504, 507 (S.D.N.Y. 2012). Several of the patients' services had already been terminated without notice of a hearing, leading to significant health consequences. *Id.* at 521-22. The court found that "[t]his loss of medical care, in contravention of federal law, constitutes irreparable injury," and that even for patients whose care had not yet

ceased, "the mere threat of a loss of medical care, even if never realized, constitutes irreparable harm." *Id* at 522 (emphasis in the original).

So too here. DEA's original inaction, and now its denial, has prohibited Ascent from getting its much-needed ADHD medications to patients and effectively shut down its business, exacerbating the public health crisis. Indeed, in March 2022 alone, Ascent produced 108 million pills, which included 13 controlled-substance medications, eight of which treat ADHD. In the month of August 2023, it produced only 135,000 pills for one ADHD treatment. Sabella Decl. ¶ 10. As in *Leddy*, the harm to Ascent, as well as the "harm to [] patients" and "harm to the community" will be irreparable. 617 F. Supp. 3d at 122.

2. **Harm to Ascent**. In addition to harming patients, DEA's arbitrary Quota Denial causes irreparable harm to Ascent. Ascent is already on the verge of collapse. Its manufacturing has nearly grounded to a halt; it has already lost more than 100 employees. Sabella Decl. ¶ 13. The Quota Denial inflicts the final deathblow.

Courts uniformly consider a business's demise as irreparable harm. For example, in *Semmes Motors, Inc. v. Ford Motor Co.*, the Second Circuit affirmed a finding of irreparable harm where a 20-year-old family-run car dealership was threatened with the loss of its franchise by the manufacturer. 429 F.2d 1197, 1205 (2d Cir. 1970). The court held that termination of the franchise would "obliterate" the dealership and that the right to continue a business "is not measurable entirely in

monetary terms." *Id.; see also Tom Doherty Assocs., Inc. v. Saban Ent., Inc.*, 60 F.3d 27, 38 (2d Cir. 1995) (affirmed granting of preliminary injunction, explaining "[w]here the loss of a product will cause the destruction of a business itself . . . the availability of money damages may be a hollow promise and a preliminary injunction appropriate."); *Roso-Lino Beverage Distributors, Inc. v. Coca-Cola Bottling Co. of New York*, 749 F.2d 124, 125–26 (2d Cir. 1984) (irreparable harm from loss of "ongoing business representing many years of effort and the livelihood of its husband and wife owners").

Without this Court's action, Ascent can get no relief. Ascent cannot sue DEA for monetary loss due to sovereign immunity. 5 U.S.C. § 702. In these circumstances, the unrecoverable monetary loss "may amount to irreparable harm" by itself. *Regeneron Pharms., Inc. v. United States Dep't of Health & Hum. Servs.*, 510 F. Supp. 3d 29, 39 (S.D.N.Y. 2020).

Regeneron is instructive. There, the court granted a preliminary injunction to a pharmaceutical manufacturer, which sought to enjoin—what amounted to—a mandatory discount for a medication it manufactured. *Id.* at 35-37. The court found that the plaintiff's loss could not be recovered against HHS under principles of sovereign immunity, supporting a finding of irreparable harm. *Id.* at 39 (noting that the Eighth, Tenth and Eleventh Circuits "have held that unrecoverable damages may be irreparable harm, without reference to the amount of the loss."). The court also

found irreparable harm because the plaintiff established that it was losing new business and customers and would have to renegotiate contracts. *Id.* at 39-40 ("[A] loss of existing business and a decline in the opportunity for new business may qualify as irreparable harm.") (citations omitted).

As defendants, HHS and DEA are apples-to-apples. DEA enjoys immunity from suits for damages, and thus no future judicial decision can repair Ascent's reputational harm, lost sales, or disrupted business relationships—even if Ascent (somehow) managed to stay in business. Ascent has lost 70% of its projected revenues; endured damaged business relationships; is in danger of breaching financial covenants with banks; and has delayed all new R&D launches due to lack of raw material quotas, causing millions of dollars in lost investments. Sabbella Decl ¶ 12-15. In addition, Ascent sells approximately 98% of its products to corporate affiliate Camber Pharmaceuticals Inc., which has incurred multi-million-dollar penalties for failing to supply Ascent's products under its customer contracts. *Id.* ¶ 15.

In short, the harm is both unrecoverable and catastrophic, amounting to the requisite showing of irreparable harm.

B. Ascent Will Succeed on the Merits

To meet its burden for an injunction, Ascent must demonstrate a "clear or substantial likelihood of success on the merits." *Yang*, 960 F.3d at 127-28.

Demonstrating a likelihood of success on the merits means that the movant presents a "substantial case" when a serious legal question is involved. *Semmes Motors, Inc.*, 429 F.2d at 1205–06.

Because the CSA does not specify a legal standard in reviewing DEA's quota decisions, the Administrative Procedure Act provides the applicable standards. *See Visels Drug Store, Inc. v. Drug Enf't Agency*, 593 F. App'x 12, 13-14 (2d Cir. 2014). Pursuant to 5 U.S.C. § 706(2)(A), a court must set aside agency action it finds to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." *See Tourus Records, Inc. v. DEA*, 259 F.3d 731, 736 (D.C. Cir. 2001). A decision is arbitrary and capricious if "the agency . . . entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Morall v. Drug Enf't Admin.*, 412 F.3d 165, 177 (D.C. Cir. 2005) (citation omitted). A court should reject a challenge if the ageny's decision "examined the relevant data" and "articulated a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *Id.* (citation omitted) (alteration in original).

Nothing of the sort occurred here. For four separate reasons, the Court should strike DEA's decision and direct it to approve Ascent's requested quotas. The Quota

Denial (i) is conclusory on its face, (ii) is founded on errors, (iii) ignores key evidence, and (iv) was issued in bad faith.

1. The Quota Denial Itself is Conclusory and Fails to Provide Adequate Reasons for DEA's Decision

As a threshold matter, DEA has failed to set forth any nonconclusory reasons for denying the Quota Applications. That failure should ordinarily "end appellate consideration," leading to the requested relief. *Tourus*, 259 F.3d 731 at 737. A "fundamental" requirement of administrative law is that an agency explains the reasons for its decision. A failure to do so, by definition, "constitutes arbitrary and capricious agency action." *Id.* Here, the Quota Denial is devoid of any substantive reasons for the decision. It merely states that DEA "lacks confidence" in the data provided by Ascent in its Quota Applications.[9]

Courts consistently hold that an agency action supported only by threadbare and conclusory reasoning cannot survive an APA challenge. In that way, *Touros* is on point. There, DEA denied claimant's application for leave to proceed in forma pauperis in a forfeiture proceeding. 259 F.3d at 737. The D.C. Circuit found DEA's denial letter to be devoid of adequate reasons for its decision. *Id.* Although the court found other reasons in the agency record to be sufficient, the court found that

[9] In fact, quota applications neither include, nor are required to include, supporting "data"—so even DEA's barebones rationale is a *non sequitur*. It was, seemingly, an oblique reference to the audit.

the letter did "not meet the APA standard" or "articulate a satisfactory explanation for the agency's decision." *Id.* (citation omitted). The letter in *Touros*, as here, was "not a statement of reasoning, but of conclusion."[10] *Id.*

This Circuit's precedent does not diverge from *Touros*. In *Visels Drug Store, Inc.*, a pharmacy challenged DEA's refusal to allow it to employ a convicted felon as a clerk without direct access to controlled-substance storage. 593 F. App'x at 13-14. The court found fault with the denial letter, which failed "to provide any such explanation or rational connection to support" its decision. *Id.* The same is true here.

2. The Quota Denial Is Founded On Errors

But the missing rationale in the Quota Denial only scratches the surface of its problems: to the extent is implicitly relies on the OTSC, *see* Footnote 9 *supra*, that document is embarrassingly flawed and erroneous. Four basic problems are obvious.

First, DEA claimed that Ascent failed to produce three documents, *see* OTSC ¶¶ 37-40, which allegedly violated its obligation to make documentation readily available to DEA. Putting aside the mountain-out-of-a-mole-hill problem (Ascent *produced* tens of thousands of documents), the agency is, embarrassingly,

[10] Although a *post hoc* explanation ultimately saved the decision in *Touros*, nothing can save DEA's decision here: the rationale allegedly backing the decision, as described below, is manifestly flawed.

wrong. Ascent actually produced two of these documents, and DEA never requested the third. *See* Jayaraman Decl. ¶ 44.

Second, DEA claims Ascent had discrepancies in certain records required to be kept pursuant to DEA regulations (DEA Forms 222), *see* OTSC, ¶¶ 16-38. These forms are required to record the distribution of certain controlled substances. However, these alleged the discrepancies were between final version and draft versions—DEA identified no errors in the final forms. Tongring Decl. ¶ 24-25. Ascent produced these draft-working copies in response to DEA's own requests.[11] It is not a regulatory violation for draft forms to contain errors—only the final copies of the DEA Forms 222 matter. Tongring Decl. ¶ 25.

Third, DEA improperly attributes purported errors by a third-party logistics company, R&S Solutions, to Ascent. *See* OTSC ¶¶ 43-44. Critically, Ascent has no control over R&S Solutions' recordkeeping practices. Jayaraman Decl. ¶ 43. Faulting Ascent for R&S's alleged mistakes is a clear error. Tongring Decl. ¶ 30.

Fourth, DEA highlights a raft of minor, clerical errors that are entirely common in the context of the thousands of shipments that must be tracked. *See* Tongring Decl. ¶ 27 (describing form entry error). In one Kafkaesque example,

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[11] If Ascent had failed to provide the draft copies, DEA would have claimed that Ascent was not being forthright. And Ascent called out its production of draft working copies during the audit, so there is no excuse for DEA having missed the point.

DEA complains that, on a few forms, Ascent drew a line on the DEA Form 222 to indicate certain line items that were not shipped but omitted the word "cancelled" along with the strike-through text. OTSC ¶¶ 20-21. Such minor clerical errors are both common and correctable. Pechnick Decl. ¶ 26. More, DEA never uses these trivial errors to deny quota—literally, the Quota Denial is "without precedent." *Id.* at ¶ 25.

Thus, in a very real way, the Quota Denial runs counter to the evidence before the agency and is deficient for that reason as well. *Morall*, 412 F.3d at 177.

3. DEA Ignored Relevant Evidence and Context

In addition to these serious errors, DEA also entirely ignored relevant mitigating evidence and context. *Morall* offers an appropriate lens through which to review this matter.

There, an administrative law judge heard testimony about "egregious" recordkeeping violations. But the ALJ found significant mitigating circumstances, declining to sanction a doctor. 412 F.3d at 166. The mitigating evidence included the short duration of the violations and the absence of any evidence of diversion. *Id.* The Deputy Administrator rejected the mitigating evidence and revoked the doctor's registration anyway. *Id.* On review, the Court said "not so fast": it found the decision arbitrary and capricious, having "entirely ignored relevant evidence," and

finding the agency made "stunningly one-sided" conclusions. *Id*. at 178. It vacated and reinstated the doctor. *Id*.

Morall applies here with force. DEA ignored relevant mitigating evidence. Because of Ascent's complete cooperation, DEA has had access to and reviewed years of company records. Jayaraman Decl. ¶ 21. Notwithstanding the breadth of DEA's audit, the purported discrepancies span a relatively brief period. The alleged deficiencies are, in some cases, erroneous and, in others, correctable, clerical errors. In addition, Ascent hired an expert to conduct a thorough review of its compliance and recordkeeping practices. Tongring Decl. ¶ 12-13. DEA's decision does not consider this context. Nor did it consider the public health crisis stemming from the shortage of ADHD medicines. DEA has charged blindly ahead, denying the Quota Applications and seeking the OTSC to revoke Ascent's registration. DEA's failure "to consider contradictory record evidence" is arbitrary and capricious. *Morall* at 167.

4. DEA Issued The Quota Denial In Bad Faith

"Proof of subjective bad faith by [agency decision-makers], depriving a [petitioner] of fair and honest consideration of its proposal, generally constitutes arbitrary and capricious action." *Tummino v. Torti*, 603 F. Supp. 2d 519, 542 (E.D.N.Y. 2009), *amended sub nom. Tummino v. Hamburg*, No. 05-CV-366 ERK VVP, 2013 WL 865851 (E.D.N.Y. Mar. 6, 2013) (citation omitted). In *Tummino*,

the court found FDA's denial of a petition that sought nonprescription availability for women of all ages of "Plan B" contraceptive to be arbitrary and capricious. *Id.* at 545. FDA's "repeated and unreasonable delays" and "significant departures from the FDA's normal procedures and policies" contributed to the court's finding that FDA's denial lacked good faith and reasoned agency decision-making. *Id.* at 544.

So too here. DEA's initial delay is unprecedented. *See* Pechnick Decl. ¶ 25.[12] The scope of its audit departs from standard practice for review of quota applications. *See id.* ¶ 25. DEA strung Ascent along, and then, as icing on the cake, it denied the application two days after Ascent finally filed suit to force a decision, an act of pure retaliation. It did so despite an ongoing public-health crisis, making the decision "particularly problematic." *Id.* These factors support an inference of bad faith, which renders the Quota Denial arbitrary and capricious.

C. Public Interest and Balance of Equities Favors Ascent

The last considerations weigh heavily in favor of Ascent. Granting the relief addresses an urgent public health need and allows a 12-year-old, minority-owned business to survive. It would not prejudice DEA at all.

Courts have recognized that the public interest strongly favors issuance of emergency relief when public health would be harmed absent the injunction. *See*

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[12] The average time DEA takes to respond to these routine, standardized applications is 6-8 weeks. *See id*. at ¶ 15.

Leddy, 617 F. Supp. 3d at 125 ("As the involuntary closure of the subject medical practice would severely, if not irrevocably, harm thousands of patients receiving medical care, the public interest overwhelmingly favors issuance of a TRO.") The medical community has recognized the critical role medication plays in treating ADHD. *See, e.g.,* Walden Decl. Ex. 7, at 2 (study finding Adderall "significantly improved" outcomes for people with ADHD"); Walden Decl. Ex. 8, at 1-2 (study finding stimulants are associated with a reduced risk of suicide attempts in patients with ADHD).

The shortage of medication to treat ADHD presents an imminent and irreparable harm for patients, primarily children, in need of these medications nationwide. *See* Walden Decl. Ex. 4, at 1-2. FDA and two Congressional offices have made direct outreach to Ascent. Jayaraman Decl. ¶ 30. With approval of the Quota Applications, Ascent would be able to get much-needed ADHD medications to patients and alleviate the shortage.

Also, Ascent faces the imminent, nonspeculative threat of shuttering its business. Sabbella Decl ¶ 16. Hundreds of jobs would be lost, and the opportunity to jump-start a once-thriving manufacturer to help alleviate the drug shortage would also be lost. *Id.* ¶ 11-14. Where a company faces the prospect of shuttering its business, courts commonly find that the balance of hardships favors the imperiled company. *See, e.g., Semmes Motors, Inc.,* 429 F.2d at 1205 ("imbalance of

hardships" in favor of plaintiff where it would lose its business); *725 Eatery Corp. v. City of New York*, 408 F. Supp. 3d 424, 469 (S.D.N.Y. 2019) (same).

On the other hand, granting emergency relief here would not prejudice DEA at all. Ascent has been in business for more than ten years, during which it has participated in approximately 13 audits conducted by FDA and has never had regulatory issues prior to DEA's recent audits. Jayaraman Decl. ¶ 13. To the extent DEA has valid concerns, they will be rectified by Ascent's continuing cooperation with the agency. *Id.* ¶ 35. Moreover, granting the requested relief is consistent with DEA's mandate to ensure the country has sufficient drugs "necessary to maintain the health and general welfare of the American people." 21 U.S.C. § 801(1).

The balance of equities thus weighs entirely in Ascent's favor.

CONCLUSION

For the foregoing reasons, this Court should compel DEA to approve Ascent's Quota Applications.

Dated: New York, NY
October 4, 2023

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

Jim Walden, an attorney at Walden Macht & Haran LLP, hereby certifies that this motion complies with the typeface and volume limitations of Rules 27 and 32 of the Federal Rules of Appellate Procedure because this motion contains 4,994 words, excluding the parts of the motion exempted by Fed. R. App. P. 27(d), and has been prepared in a proportionally spaced typeface using Microsoft Word in Times New Roman 14-point font, in accordance with Fed. R. App. P. 32(a)(5)-(6).

Dated: New York, NY
October 4, 2023

/s/ *Jim Walden*
Jim Walden

CERTIFICATE OF SERVICE

Jim Walden, an attorney at Walden Macht & Haran LLP, hereby certifies that on October 4, 2023, the foregoing Emergency Motion for Mandatory Preliminary Injunctive Relief was filed with the Clerk of the Court for the United States Court of Appeals for the Second Circuit by using the appellate CM/ECF system. All participants in the case are registered CM/ECF users and will be served by the appellate CM/ECF system.

Dated: New York, NY
October 4, 2023

/s/ *Jim Walden*
Jim Walden