

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

ALCRESTA THERAPEUTICS, INC. *et al.*,

Plaintiffs,

v.

ALEX M. AZAR II, Secretary of Health and
Human Services,

Defendant.

Civil Action No. 18-243 (TJK)

MEMORANDUM OPINION AND ORDER

On June 26, Plaintiffs filed an Emergency Motion (the “Emergency Motion”) for an Injunction Pending Appeal of the Court’s Order denying their Motion for Preliminary Injunction. *See* ECF No. 50 (“Emer. Mot.”). For the reasons set forth below, the Emergency Motion is denied.

I. Background

On February 2, 2018, Plaintiffs Alcresta Therapeutics, Inc. (“Alcresta”) and Jonathan Flath filed suit against the Secretary of Health and Human Services, alleging that the agency improperly failed to grant Alcresta a new billing code for one of its products, Relizorb. ECF No. 1. More than three weeks later, Plaintiffs filed an Amended Complaint, ECF No. 7, and a Motion for Preliminary Injunction (the “PI Motion”), ECF No. 8. At the parties’ request, the Court stayed its consideration of the PI Motion while they discussed a potential settlement.

After settlement talks broke down, the Court held oral argument on the PI Motion and subsequently issued an Order denying the PI Motion, ECF No. 47, and an accompanying Memorandum Opinion (“PI Opinion”), ECF No. 48. The instant opinion assumes familiarity with the facts of the case as described in the PI Opinion. *Id.* at 1-9. In denying the PI Motion,

the Court concluded that, based on the record, Alcresta was not entitled to a preliminary injunction because it failed to establish that absent an injunction, it would suffer irreparable harm. *Id.* at 10-15. The Court also concluded that Flath, a patient with cystic fibrosis who had taken Relizorb for a few months, was not entitled to a preliminary injunction because: (1) he failed to demonstrate a substantial likelihood of standing, which is necessary to establish a likelihood of success on the merits; and (2) he failed to establish irreparable harm because the preliminary relief sought—including a temporary new billing code for Relizorb—would not cause government insurers to reimburse for Relizorb, and thus would not remedy the irreparable harm Flath had alleged. *Id.* at 1, 15-24.

On June 26, Plaintiffs appealed the Court’s Order, ECF No. 51 (notice of appeal), and filed the instant Emergency Motion. The Emergency Motion seeks an injunction pending appeal resembling the preliminary injunction Plaintiffs requested earlier. Plaintiffs request that this Court order that Defendant (1) adhere to the Federal Advisory Committee Act (“FACA”) and other required procedures in considering Alcresta’s 2018 application for a permanent, unique billing code, (2) issue a “reasoned decision” on Alcresta’s 2017 application, and (3) issue a “valid, usable temporary code” for Relizorb in the interim. Emer. Mot. at 1-2; *see also* PI Motion at 1. On June 27, Defendant filed his response. ECF No. 53.

II. Legal Standard

Federal Rule of Civil Procedure 62(c) provides that “[w]hile an appeal is pending from an interlocutory order . . . that . . . denies an injunction, the court may suspend, modify, restore, or grant an injunction on terms for bond or other terms that secure the opposing party’s rights.” “[I]njunction pending appeal is an extraordinary remedy.” *Memphis Publ’g Co. v. FBI*, 195 F. Supp. 3d 1, 3 (D.D.C. 2012) (citing *Cuomo v. U.S. Nuclear Regulatory Comm’n*, 772 F.2d 972, 978 (D.C. Cir. 1985)). “The standards for evaluating a motion for an injunction pending appeal

are ‘substantially the same as those for issuing a preliminary injunction.’” *Amgen Inc. v. Azar*, No. 17-cv-1006, 2018 WL 1990521, at *1 (D.D.C. Feb. 22, 2018) (quoting *Al-Anazi v. Bush*, 370 F. Supp. 2d 188, 199 n.11 (D.D.C. 2005)). Plaintiffs “must establish that [they are] likely to succeed on the merits, that [they are] likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in [their] favor, and that an injunction is in the public interest.” *Id.* (quoting *Winter v. Nat. Res. Def. Council, Inc.* 555 U.S. 7, 20 (2008)).

III. Analysis

In their Emergency Motion, Plaintiffs make two broad arguments for an injunction pending appeal, both of which reflect disagreement with the Court’s reasoning in the PI Opinion. First, they argue that the D.C. Circuit uses a “sliding scale” to evaluate motions for preliminary injunctive relief, and that the Court erred by failing to apply it in the PI Opinion. Emer. Mot. at 2-3, 5. Second, Plaintiffs argue that the Court erred by concluding that they failed to demonstrate irreparable harm. *Id.* at 3-4. The Court addresses each argument in turn.

A. The Sliding Scale

“Before the Supreme Court’s decision in *Winter*, courts in this circuit applied a ‘sliding-scale’ approach under which ‘a strong showing on one factor could make up for a weaker showing on another.’” *Amgen*, 2018 WL 1990521, at *1 (quoting *Sherley v. Sebelius*, 644 F.3d 388, 392 (D.C. Cir. 2011)). In *Winter*, the Supreme Court rejected the argument that “when a plaintiff demonstrates a strong likelihood of prevailing on the merits, a preliminary injunction may be entered based only on a ‘possibility’ of irreparable harm.” 555 U.S. at 21. Instead, plaintiffs seeking preliminary relief must “demonstrate that irreparable injury is *likely* in the absence of an injunction.” *Id.* at 22. “Some judges of the D.C. Circuit have expressed the view that . . . *Winter* supplants the ‘sliding scale’ approach, and a movant cannot obtain an injunction without showing ‘*both* a likelihood of success *and* a likelihood of irreparable harm.’”

Soundboard Ass’n v. FTC, 254 F. Supp. 3d 7, 9-10 (D.D.C. 2017) (quoting *Sherley*, 644 F.3d at 392). But the D.C. Circuit “has not yet needed to decide th[e] issue.” *League of Women Voters of U.S. v. Newby*, 838 F.3d 1, 7 (D.C. Cir. 2016).

Against this backdrop, Plaintiffs argue that the “sliding scale” governs the Emergency Motion and that the PI Opinion misapplied that standard, because it did not conduct a full analysis of their likelihood of success on the merits or the balance of equities. Emer. Mot. at 2-3. As an initial matter, the Court has strong doubts that the sliding-scale approach survives *Winter*. See, e.g., *Nken v. Holder*, 556 U.S. 418, 438 (2009) (“When considering success on the merits and irreparable harm, courts cannot dispense with the required showing of one simply because there is a strong likelihood of the other.” (Kennedy, J., concurring)); *Davis v. Pension Benefit Guar. Corp.*, 571 F.3d 1288, 1296 (D.C. Cir. 2009) (“[U]nder the Supreme Court’s precedents, a movant cannot obtain a preliminary injunction without showing *both* a likelihood of success *and* a likelihood of irreparable harm, among other things.” (Kavanaugh, J., concurring)); *Guttenberg v. Emery*, 26 F. Supp. 3d 88, 100 n.5 (D.D.C. 2014) (“Even a narrow reading of the Court’s holding in *Winter* supports the view that sliding-scale analysis is obsolete.”).¹

But “[w]hether or not *Winter* spelled the end of sliding-scale analysis, one thing is clear: plaintiffs here must at least ‘demonstrate that irreparable injury is *likely* in the absence of an injunction.’” *Guttenberg*, 26 F. Supp. 3d at 101 (quoting *Winter*, 555 U.S. at 22). “Under *Winter*, even a ‘strong likelihood of prevailing on the merits’ cannot make up for a deficient

¹ Plaintiffs seem to suggest that even if the sliding-scale approach does not apply to a motion for a preliminary injunction, it nevertheless applies to a motion for injunction pending appeal. See Emer. Mot. at 2-3. There is no reason to believe this is the case. The tests for both motions are “substantially the same.” *Amgen*, 2018 WL 1990521, at *1. Tellingly, the only case Plaintiffs cite for this counterintuitive proposition pre-dates *Winter* by more than 20 years, and thus has no bearing on the present viability of the sliding-scale approach. See Emer. Mot. at 2 (citing *Population Inst. v. McPherson*, 797 F.2d 1062, 1078 (D.C. Cir. 1986)).

showing of irreparable injury.” *Id.* (quoting *Winter*, 555 U.S. at 21-22). As the Court explained in its PI Opinion, Plaintiffs have failed to demonstrate that they are “likely” to suffer irreparable harm in the absence of an injunction. PI Opinion at 10-15, 22-24. Thus, they are not entitled to a preliminary injunction, and the Court need not analyze the remaining factors to reach this conclusion. *See, e.g., Chaplaincy of Full Gospel Churches v. England*, 454 F.3d 290, 297 (D.C. Cir. 2006) (“A movant’s failure to show any irreparable harm is therefore grounds for refusing to issue a preliminary injunction, even if the other three factors entering the calculus merit such relief.”); *CityFed Fin. Corp. v. OTS*, 58 F.3d 738, 747 (D.C. Cir. 1995) (“[Plaintiff] has made no showing of irreparable injury here, [and] that alone is sufficient for us to conclude that the district court did not abuse its discretion by rejecting [plaintiff’s] request.”); *Mdewakanton Sioux Indians of Minn. v. Zinke*, 255 F. Supp. 3d 48, 51 & n.3 (D.D.C. 2017) (“Regardless of how the other three factors are analyzed, it is required that the movant demonstrate an irreparable injury.”).

In fact, the D.C. Circuit has upheld the denial of a motion for an injunction pending appeal where the plaintiff has failed to establish irreparable harm. *See FTC v. Weyerhaeuser Co.*, 648 F.2d 739, 743 (D.C. Cir. 1981) (“[T]he FTC . . . has failed to show irreparable harm. For this reason alone an injunction pending appeal is unwarranted.”).² Here too, where the Court

² “[M]otions for an injunction pending appeal are governed by the same standard as motions for stay pending appeal” *McCammon v. United States*, 584 F. Supp. 2d 193, 196 (D.D.C. 2008). Courts have also denied motions to stay pending appeal on the ground that the movant has failed to show irreparable harm. *See, e.g., Nat’l Ass’n of Mfrs. v. NLRB*, No. 11-cv-1629, 2012 WL 1929889, at *1 (D.D.C. Mar. 7, 2012) (“[T]he movant’s failure to make any showing of irreparable harm is grounds for refusing to grant a stay [pending appeal], even if the other three factors merit relief.”).

has found that Plaintiffs have not shown a likelihood of irreparable harm, the Court must deny the Emergency Motion.³

B. Irreparable Harm

Plaintiffs also argue that an injunction pending appeal is justified because the Court purportedly “disregarded” three arguments that they are suffering irreparable harm: (1) Flath’s inability to obtain Relizorb and the alleged inability of patients taking Relizorb generally to submit claims under Medicare; (2) Alcresta’s alleged loss of \$15 million in profits, which Plaintiffs claim are not recoverable; and (3) the procedural injury related to the government’s alleged failure to comply with FACA. Emer. Mot. at 3. But none of these alleged harms is sufficient to demonstrate irreparable harm.

First, the Court explained in the PI Opinion that Flath failed to establish irreparable harm because the injunction he sought would not remedy the harm he alleged. PI Opinion at 22-24. Flath’s alleged harm stems from the fact that government insurers do not fully reimburse for Relizorb. But the injunctive relief he seeks would only order Defendant to take various actions regarding Relizorb’s billing code. Emer. Mot. at 1-2. As the Court has already explained, there is a “fundamental disconnect” between the irreparable harm alleged and the injunctive relief sought because changing the billing code used for Relizorb will not lead government insurers to

³ Plaintiffs assert that the D.C. Circuit “has made clear that, even assuming ‘the showing of irreparable harm to the movant [is] very low,’ the court [must] proceed[] to consider the other three factors.” Emer. Mot. at 3 (quoting *Davis*, 571 F.3d at 1292); *see also id.* (“[B]ecause in considering this motion the Court weighs all of those factors” (citing *Davis*, 571 F.3d at 1292)). That is not correct. The D.C. Circuit has explicitly held that a request for a preliminary injunction or a request for an injunction pending appeal can be denied purely on the basis of failure to establish irreparable injury. *Chaplaincy*, 454 F.3d at 297; *CityFed Fin. Corp.*, 58 F.3d at 747; *Weyerhaeuser*, 648 F.2d at 743. *Davis* is not to the contrary. It simply describes the historical sliding-scale approach which, as *Davis* itself noted, may no longer be good law. 571 F.3d at 1292. Even under the historical approach, if, as here, plaintiffs have “failed to show irreparable harm,” then “[f]or this reason alone an injunction pending appeal is unwarranted.” *Weyerhaeuser*, 648 F.2d at 743.

provide additional reimbursement for the product. PI Opinion at 2, 22-24. For similar reasons, the Court also concluded that Flath failed to establish a substantial likelihood of standing. *Id.* at 15-22.

Plaintiffs also have not established irreparable harm resulting from patients' inability to submit a Medicare claim for Relizorb. As noted in the PI Opinion, Defendant has submitted a sworn and un rebutted declaration establishing that billing code B4035 remains a valid Medicare billing code for Relizorb and provides patients access to the claims and appeals process. *See id.* at 9; ECF No. 34-1 ¶¶ 14-15 (“[C]ode B4035 is a valid code for Medicare claims processing purposes. . . . If a Medicare claim is processed, then there is an initial determination regarding Medicare payment on the claim. Initial determinations are subject to administrative and judicial review in accordance with the Medicare statute and applicable rules, regulations, guidance, and procedures.”). In addition, to the extent Plaintiffs now invoke this theory as to “patients” other than Flath, injuries to third parties are not a basis to find irreparable harm. *See Cardinal Health, Inc. v. Holder*, 846 F. Supp. 2d 203, 213 (D.D.C. 2012) (holding argument about irreparable harm to consumers “fails because it shows irreparable harm not to [plaintiff], but to third parties”).

Second, the Court explained in detail in the PI Opinion why the lost profits Alcresta alleges do not demonstrate irreparable harm. PI Opinion at 10-15. Plaintiffs suggest that, despite the Court’s conclusion, an injunction pending appeal would be proper because there is a “split” in this Circuit on whether irrecoverable monetary losses constitute irreparable harm, and that this “difficult legal question” justifies an injunction pending appeal. Emer. Mot. at 4 (citing *Wash. Metro. Area Transit Comm’n v. Holiday Tours, Inc.*, 559 F.2d 841, 844 (D.C. Cir. 1977)). The Court does not agree. As the Court explained in the PI Opinion, the vast majority of district

court opinions in this Circuit have rejected the rule that unrecoverable monetary losses constitute per se irreparable harm. PI Opinion at 12-14. Instead, “the ‘fact that economic losses may be unrecoverable does not, in and of itself, compel a finding of irreparable harm,’ for the harm must also be great, certain and imminent.” *Cardinal Health*, 846 F. Supp. 2d at 211 (quoting *Nat’l Mining Ass’n v. Jackson*, 768 F. Supp. 2d 34, 53 (D.D.C. 2011)).⁴ As the Court explained at length in the PI Opinion, because Alcresta declined to place its alleged lost profits in the context of its overall financial health, the Court cannot find that its alleged lost profits are “certain” or “great,” as is required to grant a preliminary injunction. *Cardinal Health*, 846 F. Supp. 2d at 211; PI Opinion at 10-15. The mere existence of nonbinding legal authority that is helpful to Plaintiffs’ cause is not sufficient to justify an injunction pending appeal.

Third, on the record before the Court, Plaintiffs have not shown that their claimed procedural injury—“the government’s failure to comply with FACA in considering Alcresta’s pending application,” Emer. Mot. at 3—is sufficient to demonstrate irreparable harm.⁵ “Even in

⁴ Plaintiffs argue that *Ohio Oil Co. v. Conway*, 279 U.S. 813 (1929), stands for the proposition that irrecoverable monetary damages constitute irreparable harm. See Emer. Mot. at 4 n.3. But *Ohio Oil Co.* is actually consistent with the rule adopted by the vast majority of district court opinions in this Circuit. That case concerned “certain and irreparable” injury, namely a significant sum of taxes that the plaintiff was obligated to pay to the defendant without any possibility of recovery. See *Ohio Oil Co.*, 279 U.S. at 814. As the Court noted in the PI Opinion, Alcresta’s alleged monetary loss is far from certain—it is derived from marketing estimates whose methodology is unclear—and it is unclear how significant the losses are to Alcresta. See PI Opinion at 11-15. In any event, it is not clear that *Ohio Oil Co.* remains good law in light of subsequent Supreme Court cases on preliminary injunctions. See *Safety-Kleen, Inc. (Pinewood) v. Wyche*, 274 F.3d 846, 870 (4th Cir. 2001) (Luttig, J., concurring) (“Tellingly, the Supreme Court itself has cited *Ohio Oil Co.* only a handful of times . . . since its decision, and it has not done so at all since 1945 . . .”). Plaintiffs also cite decisions from appellate courts outside this Circuit for the same proposition they cite *Ohio Oil Co.*, Emer. Mot. at 4 n.3, but these decisions do not persuade the Court to revisit its conclusions in the PI Opinion.

⁵ The Court notes that Plaintiffs did not raise procedural injury as a basis for irreparable harm in their brief or reply brief supporting their PI Motion. See ECF Nos. 10, 21.

the FACA context, the extraordinary nature of a preliminary injunction demands that the requesting party carry the burden of demonstrating irreparable harm and inadequacy of legal remedies as a basis for such relief.” *Pub. Citizen v. Nat’l Advisory Comm. on Microbiological Criteria for Foods*, 708 F. Supp. 359, 362 (D.D.C. 1988), *aff’d*, 886 F.2d 419 (D.C. Cir. 1989). “[C]ourts generally ‘will not base a finding of “irreparable injury” on a procedural violation standing alone’” *Elk Assocs. Funding Corp. v. U.S. Small Bus. Admin.*, 858 F. Supp. 2d 1, 31 (D.D.C. 2012) (quoting *Am. Ass’n for Homecare v. Leavitt*, No. 08-cv-992, 2008 WL 2580217, at *5 (D.D.C. June 30, 2008)). More specifically, procedural injury accompanied by harm that is concrete but not “great” (as is required for a preliminary injunction) does not equate to irreparable harm. *See, e.g., Nat’l Parks Conservation Ass’n v. U.S. Forest Serv.*, No. 15-cv-01582, 2016 WL 420470, at *11 (D.D.C. Jan. 22, 2016) (“But even assuming that Defendants did violate NEPA here, that procedural harm would largely ‘stand alone’—the only identified immediate concrete injury being the permanent loss of some soil, which the court has concluded does not constitute ‘great’ injury. Accordingly, Plaintiff’s claimed procedural harm does not add sufficient weight to establish irreparable harm.”). That is precisely the situation here regarding Alcresta. As explained above, the Court cannot conclude that Alcresta’s lost profits are “great” without information concerning Alcresta’s finances, which it declined to place in the record. And the antecedent FACA-based procedural injury alleged by Plaintiffs, which in and of itself is also not “great,” does not alter that analysis.⁶ Certainly, Plaintiffs have not cited any analogous case suggesting as much.

⁶ In the PI Opinion, the Court concluded that Flath cannot rely on procedural injury to demonstrate standing because the asserted harm to his health is not traceable to a procedural injury. PI Opinion at 21 n.4. For similar reasons, any argument that he is suffering irreparable harm due to a procedural injury fails as well.

For all of the above reasons, and those specified in the PI Opinion, Plaintiffs have failed to establish that they will suffer irreparable harm absent an injunction pending appeal, and Flath has failed to demonstrate a likelihood of success on the merits because he has not established a substantial likelihood that he has standing.

IV. Conclusion

Plaintiffs' Emergency Motion for an Injunction Pending Appeal, ECF No. 50, is therefore **DENIED.**

SO ORDERED.

/s/ Timothy J. Kelly
TIMOTHY J. KELLY
United States District Judge

Date: June 28, 2018