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

Plaintiff Alcresta Therapeutics, Inc. ("Alcresta") is a pharmaceutical company that manufactures a medical device called Relizorb. Plaintiff Jonathan Flath is a cystic fibrosis patient who used Relizorb for three months. The Department of Health and Human Services ("Defendant") establishes billing codes for use in the healthcare industry. Plaintiffs filed this lawsuit against the Secretary of Health and Human Services, challenging Defendant's denial of a permanent unique billing code for Relizorb. Three weeks after Plaintiffs filed, they moved for a preliminary injunction that would provide them with a number of forms of relief, including a temporary unique billing code for Relizorb. *See* ECF No. 8 ("PI Mot." or "Motion"). To demonstrate that they are suffering irreparable harm, Plaintiffs point to Alcresta's lost profits and to the negative effect on Flath's health that they assert will result from his inability to procure Relizorb, both of which they attribute to Defendant's failure to assign it a unique billing code.

Neither plaintiff, however, has demonstrated irreparable harm that would be addressed by the injunctive relief sought. Under the law in this Circuit, Alcresta's lost profits on Relizorb, without more information on the impact of those losses on its overall financial health, simply do not establish irreparable harm. Flath's claim of irreparable harm fails for slightly different

reasons. First, his alleged harm was not caused by Defendant's decision to deny Alcresta a permanent unique billing code for Relizorb. Instead, his inability to obtain and use Relizorb is the result of a longstanding decision by Defendant (the administrator of Medicare) to provide reimbursement for enteral nutritional therapies in a manner that covers at best only a fraction of Relizorb's list price, irrespective of the billing codes these products are assigned. Second, the relief Flath requests (including the injunctive relief) is not likely to change this reimbursement decision, thereby redressing his alleged harm, as events during the pendency of this litigation bear out. In fact, after Plaintiffs filed their Motion, Defendant provided Relizorb a temporary unique billing code, but that did not facilitate a corresponding change in its reimbursement status under Medicare. In sum, there is a fundamental disconnect between Flath's alleged harm and the injunctive relief he seeks. As a result, he has failed to establish that the relief will remedy his alleged harm. For similar reasons, Flath has also failed to show a substantial likelihood that he has standing, which is necessary to establish a likelihood of success on the merits.

Plaintiffs' ultimate aim does not appear to be to obtain a unique billing code for Relizorb, but to get insurers—including Medicare—to provide full reimbursement for it. But the proper vehicle to challenge Medicare reimbursement determinations is the Medicare Act, 42 U.S.C. § 1395 *et seq.*, which requires plaintiffs to exhaust their remedies before seeking relief in this Court.

Therefore, for the reasons set forth below, Plaintiffs' Motion, ECF No. 8, will be denied.[1]

[1] In considering Plaintiffs' Motion, the Court considered all relevant filings including, but not limited to, the following: Plaintiffs' Amended Complaint, ECF No. 7 ("Am. Compl."); Declaration of James Gamgort, ECF No. 8-23 ("Gamgort Decl."); Plaintiffs' Memorandum in Support of Preliminary Injunction, ECF No. 10 ("Pls.' PI Br.") (redacted public version at ECF No. 18); Declaration of Jonathan R. Flath, ECF No. 10-1 ("Flath Decl.") (filed under seal); Defendant's Opposition to Plaintiffs' Motion for Preliminary Injunction, ECF No. 22 ("Def.'s

I. Background

A. Statutory and Regulatory Background

1. National Uniform Codes

The Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), Pub. L. No. 104-191, 110 Stat. 1936, required Defendant to establish a nationwide, standard coding system to address the difficulties posed by the lack of uniformity in healthcare billing. *See* 42 U.S.C. § 1320d-2(c)(1); HIPAA § 261, 110 Stat. at 2021. One of the standard coding systems Defendant adopted in response is known as the Healthcare Common Procedure Coding System ("HCPCS"). *See* 45 C.F.R. § 162.1002; Def.'s Opp. at 2. The Centers for Medicare and Medicaid Services ("CMS"), a component of Defendant, oversees this system. 42 C.F.R. § 414.40(a). HCPCS has two levels of billing codes. *See* Def.'s Opp. at 3. Level II codes include those for durable medical equipment ("DME"), such as prosthetics, orthotics, and supplies that are used outside a physician's office. Pls.' PI Br. at 3. Relizorb is categorized as DME by CMS regulation. Pls.' PI Br. at 3 n.2; *see also* Def.'s Opp. at 16. These billing codes are used by various insurance carriers, including commercial insurers, state Medicaid programs, and Medicare contractors. Def.'s Opp. at 3; Pls.' PI Br. at 3. They are aimed at promoting administrative efficiency, but, as the HCPCS Code Book states, assignment of a billing code does not suggest that a product will be reimbursed. *See* ECF No. 12-1 at 3 ("Inclusion or

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Opp.") (redacted public version at ECF No. 12); Plaintiffs' Reply in Support of Their Motion for Preliminary Injunction, ECF No. 21 ("Pls.' Reply") (redacted public version at ECF No. 19); Plaintiffs' Supplemental Brief in Support of Their Motion for Preliminary Injunction, ECF No. 29-1 ("Pls.' Supp. Br.") (redacted public version at ECF No. 30); Defendant's Supplemental Brief in Opposition to Plaintiffs' Motion for Preliminary Injunction, ECF No. 34; Declaration of Laurence Wilson, ECF No. 34-1 ("Wilson Decl."); Defendant's Supplemental Declaration from Laurence Wilson, ECF No. 39-1 ("Wilson Supp. Decl."); and Plaintiffs' Response to Defendant's Supplemental Facts, ECF No. 42.

exclusion of a procedure, supply, product or service does not imply any health insurance coverage or reimbursement policy.").

2. The HCPCS Workgroup

In 2000, Congress passed the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 ("BIPA"), Pub. L. 106-554, App. F, 114 Stat. 2763A-463. In it, Congress directed Defendant to establish procedures for public consultation on coding and payment determinations for new DME. *See* BIPA § 531(b), 114 Stat. at 2763A-547. To do so, Defendant adopted regulations that, among other things, created the HCPCS Workgroup (the "Workgroup"). *See* 66 Fed. Reg. 58,743, 58,744 (Nov. 23, 2001).

The Workgroup is responsible for initially assessing applications for new Level II billing codes. It is comprised of federal employees (including CMS employees), federal contractors, and state government employees. Wilson Supp. Decl. ¶ 3(1), at 2. It also used to include a representative of the insurance industry. *Id.* ¶ 3(2), at 6.

Applications for new Level II billing codes, which are due in January of a given year, are assessed annually. *Id.* ¶ 3(4), at 8. The Workgroup makes its preliminary coding determinations in the spring. *Id.* at 9. Afterward, the Workgroup hosts public meetings at which applicants and the public can provide feedback on its preliminary determinations. *Id.* Following the public meetings, the Workgroup reconvenes to reconsider all the applications in light of the feedback received. *Id.* CMS publishes its final coding decisions on or around November 1 each year. *Id.* In Plaintiffs' telling, CMS simply "rubber-stamps" the Workgroup's recommendations. Pls.' PI Br. at 33. Defendant, by contrast, asserts that it makes its own independent determinations. Wilson Supp. Decl. ¶ 3(7), at 12-13.

In addition to evaluating applications for billing codes through the annual application process, the Workgroup also issues billing codes through the HCPCS quarterly update process.

Pls.' PI Br. at 7. The quarterly update process allows temporary billing codes to be issued by CMS on its own initiative when there is an "urgent national program operating need[]." *Id.*

3. Medicare Coverage for Enteral Nutritional Therapy

Medicare, an insurance provider administered by Defendant that uses HCPCS billing codes, has a specific regulatory framework that governs how it provides reimbursement for enteral nutritional therapy products (*i.e.*, products that deliver nutrients directly to the stomach), such as Relizorb. *See* Wilson Decl. According to a declaration from the Director of the Chronic Care Policy Group within the Center for Medicare, under these payment rules, "Medicare pays an all-inclusive daily allowance that pays for all necessary enteral nutrition supplies." *Id.* ¶ 8. These rules, which have been in place "at least 35 years," mean that "[e]ven though a code may be added to the HCPCS to identify a specific individual enteral nutrition supply, the existence of a new code identifying an individual enteral supply does not mean that the supply would qualify for additional Medicare payment beyond the all-inclusive payment." *Id.* ¶ 9. Thus, "both before and after the establishment of a new code for an individual enteral supply, Medicare pays an all-inclusive payment for *all* enteral nutrition supplies." *Id.* ¶ 11.

B. Factual Background

Alcresta is a pharmaceutical company that creates and sells "enzyme-based products designed to address nutritional challenges faced by medically fragile persons." Am. Compl. ¶ 14. One of their products, Relizorb, is a device that contains a digestive enzyme that enhances the ability of an individual to absorb nutrients during enteral feeding. *Id.* ¶ 2.

Over the last few years, Alcresta has attempted to obtain a Level II billing code for Relizorb, in the hope that doing so will increase the likelihood that insurers will fully reimburse the product. In 2016, the Workgroup preliminarily (and, in Plaintiffs' view, erroneously) concluded that Relizorb was adequately described by billing codes B4034, B4035, and B4036,

meaning that it did not require a unique code. Pls.' PI Br. at 9. In its final determination for 2016, CMS reached the same conclusion, but for a different reason: it stated that there was no "national program operating need" for Relizorb to have its own billing code. *Id.* In 2017, Alcresta reapplied and, again, the Workgroup preliminarily determined that Relizorb was adequately described by billing codes B4034, B4035, and B4036. *Id.* In its final determination, CMS again denied approval of a unique code, concluding that code B4035 adequately covered Relizorb. *Id.* at 15.[2] In light of these repeated denials, Alcresta filed another application for the 2018 cycle. Pls.' PI Br. at 16.

Alcresta alleges that it is suffering financial harm because Relizorb does not have a unique billing code. Specifically, according to a declaration from its Chief Commercial Officer ("CCO"), the code assigned to Relizorb, B4035, causes Alcresta to lose money in two ways. First, once a claim has been submitted on behalf of a patient under a given billing code, another claim may not be submitted for that patient under that code in the same time frame. Gamgort Decl. ¶ 6. Thus, if a claim for a month's supply of Relizorb is submitted under code B4035, it will not be reimbursed if a claim for any other product (*e.g.*, an enteral feeding tubing or another inert enteral feeding kit item) has been submitted under the same code for the same patient that month. *Id.* Medicare has denied reimbursement claims for Relizorb on this basis. *Id.* Second, even when payments for Relizorb have been made under code B4035, they are at the per diem rate authorized for inert enteral feeding kit supplies, approximately $5-$10, not Relizorb's list price of $53. *Id.* ¶ 7. As a result, Alcresta's CCO estimates that the company lost approximately

[2] A "miscellaneous" HCPCS code, B998, also exists. According to Plaintiffs, Medicare will not accept claims for Relizorb under this code, Gamgort Decl. ¶ 13, and while "[s]ome" Medicaid plans will, coverage is determined on a "patient-by-patient basis," *id.* ¶ 20.

$15.3 million in revenue in 2017—and expects even greater losses this year—which he alleges is "due to the lack of insurance coverage associated with the denial of a unique code for Relizorb." *Id.* ¶ 22.

Flath is a patient who has cystic fibrosis, and as a result he suffers from fat malabsorption. Am. Compl. ¶ 4. He was recently provided Relizorb for three months, and he states, in a filing made under seal, that switching from other enteral feeding products to Relizorb significantly improved his health. Flath Decl. ¶¶ 32-39, 41-43. Flath cannot afford to pay for Relizorb out of pocket. *Id.* ¶ 43. In February 2018, Flath was informed by the supplier of Relizorb that he would not be able to continue to receive it because, while he is eligible for Medicare and Medicaid, they do not provide full reimbursement for it. *Id.* ¶¶ 40, 43; Gamgort Decl. ¶ 7. As Flath understands it, his supplier cannot bill Medicare for Relizorb "due to a coding issue, and therefore a claim to Medicaid is not an option." Flath Decl. ¶ 43.

C. Procedural Background

On February 2, 2018, Plaintiffs filed their original complaint in this matter. *See* ECF No. 1. More than three weeks later, on February 27, 2018, Plaintiffs filed an amended complaint, Am. Compl., and a Motion for Preliminary Injunction, PI Mot. In their Amended Complaint, Plaintiffs bring four counts under the Administrative Procedure Act, 5 U.S.C. § 551 *et seq.* *See* Am. Compl. ¶¶ 121-122. They are that: (1) Defendant's decision on Alcresta's 2017 application was not supported by substantial evidence; (2) it was arbitrary and capricious; (3) criteria used in the Workgroup's decisionmaking process should have been approved through notice and comment procedures; and (4) the Workgroup is subject to the Federal Advisory Committee Act ("FACA"), 5 U.S.C. App. 2 § 1 *et seq.*, which Defendant violated by failing to open Workgroup meetings to the public and delegating agency decisionmaking to the Workgroup. *See* Am. Compl. ¶¶ 123-171. Plaintiffs seek a variety of forms of relief, including: declaring some of

Defendant's past actions concerning Relizorb's billing code invalid; directing it to reconsider Alcresta's 2017 application and use proper procedures in considering its 2018 application; requiring it to provide a temporary unique billing code for Relizorb; and enjoining it from violating FACA and relying on the Workgroup's decisions on Relizorb. Am. Compl. at 50-51.

In their Motion, Plaintiffs request an injunction requiring Defendant to: (1) "[s]trike Relizorb from the list of products included in existing billing codes B4034, B4035, and B4036"; (2) "issue a temporary, unique code that includes Relizorb through the HCPCS quarterly update process"; (3) "make an independent decision" on Alcresta's 2017 application "based on all of the relevant evidence and valid, applicable criteria"; and (4) "[a]dhere to proper administrative procedure" in considering Alcresta's 2018 application "or in otherwise considering HCPCS coding for Relizorb." PI Mot. at 1.

On March 22, the parties filed a joint motion requesting that the Court continue a hearing, then scheduled for March 23, on the Motion because the parties had "reached an agreement in principle . . . that obviates the immediate need for the hearing . . . and may obviate the need for further consideration of the motion." ECF No. 20. Subsequently, Defendant took a number of actions that, in Defendant's view, effectively granted Plaintiffs all of the relief they requested. Defendant "removed Relizorb from the products listed in existing billing codes B4034, B4035, and B4036," and it issued Relizorb a temporary unique billing code, effective July 1, 2018. *See* ECF No. 24 at 3. It also "rescinded" its decision Alcresta's 2017 application and claimed that it was "in the process of adhering to proper administrative procedure" in evaluating its 2018 application. *Id.*[3]

[3] On May 15, Plaintiffs notified the Court that CMS is "delaying its preliminary coding recommendation [on Alcresta's 2018 application] for Relizorb pending further consideration of this matter." ECF No. 43 at 1.

These actions, however, did not achieve Plaintiffs' goal of making Relizorb fully reimbursable under Medicare. *See* ECF No. 25. When Defendant created a new temporary unique billing code for Relizorb (Q9994), it appended an "indicator" denoting that the device is "not payable" at all by Medicare under that code. Wilson Decl. ¶ 13; *see* ECF No. 25 at 2. In other words, even though Defendant removed Relizorb as a product listed under billing code B4035 as Plaintiffs' requested, that code nevertheless remains the valid billing code for Relizorb, at least for Medicare claims. Wilson Decl. ¶ 14. The newly-created temporary code Q9994, by contrast, "is not valid for Medicare claims processing purposes," but private insurers are free to use it. *Id.* Regardless of which code is valid for what purpose, however, the bottom line is that the new code does not qualify Relizorb for any additional payment under Medicare, beyond the all-inclusive payment already available under code B4035. *Id.* ¶ 13.

Plaintiffs believe their position has actually worsened after Defendant's actions. Now, as they point out, not only will Medicare continue to reject full reimbursement for Relizorb, but the indicator appended to the new code also sends a "detrimental signal to health care plans in the industry," Pls.' Supp. Br. at 5, making it less likely that other insurers will agree to provide full reimbursement for it.

On April 17, the Court held oral argument on the Motion. ECF No. 41 ("Oral Arg. Tr.").

II. Legal Standard

A preliminary injunction is "an extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief." *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 22 (2008). To warrant a preliminary injunction, plaintiffs must establish that: (1) they are "likely to succeed on the merits"; (2) they are "likely to suffer irreparable harm in the absence of preliminary relief"; (3) that the "balance of equities" tips in their favor; and (4) that "an injunction is in the public interest." *Id.* at 20. "[T]he movant must show that the alleged

harm will directly result from the action which the movant seeks to enjoin." *Wis. Gas Co. v. FERC*, 758 F.2d 669, 674 (D.C. Cir. 1985). Moreover, the last two factors "merge when the Government is the opposing party." *Nken v. Holder*, 556 U.S. 418, 435 (2009). "When moving the court for a preliminary injunction, plaintiffs bear the burdens of production and persuasion." *Qualls v. Rumsfeld*, 357 F. Supp. 2d 274, 281 (D.D.C. 2005) (citing *Cobell v. Norton*, 391 F.3d 251, 258 (D.C. Cir. 2004)).

III. Analysis

A. Alcresta

The Court concludes that Alcresta is not entitled to a preliminary injunction because it has failed to establish irreparable harm.

1. Irreparable Harm

"[T]he basis of injunctive relief in the federal courts has always been irreparable harm." *Chaplaincy of Full Gospel Churches v. England*, 454 F.3d 290, 297 (D.C. Cir. 2006) (quoting *Sampson v. Murray*, 415 U.S. 61, 88 (1974)). "The irreparable injury requirement erects a very high bar for a movant." *Coal. for Common Sense in Gov't Procurement v. United States*, 576 F. Supp. 2d 162, 168 (D.D.C. 2008). To be entitled to such relief, a plaintiff must show injury that is "certain, great, actual, and imminent." *Mylan Labs. Ltd. v. FDA*, 910 F. Supp. 2d 299, 313 (D.D.C. 2012) (citing *Wis. Gas Co.*, 758 F.2d at 674). "Mere injuries, however substantial, in terms of money, time and energy necessarily expended in the absence of a stay are not enough" when "adequate compensatory or other corrective relief will be available at a later date." *Wis. Gas Co.*, 758 F.2d at 674 (quoting *Va. Petrol. Jobbers Ass'n v. Fed. Power Comm'n*, 259 F.2d 921, 925 (D.C. Cir. 1958)).

Alcresta asserts that the financial losses that it has suffered as a result of not having a permanent unique billing code for Relizorb constitute irreparable harm. Pls.' PI Br. at 37-38.

Specifically, Alcresta has submitted a declaration from its CCO alleging that the company lost approximately $15.3 million in revenue in 2017—and expects even greater losses this year—"due to the lack of insurance coverage associated with the denial of a unique code for Relizorb." Gamgort Decl. ¶ 22.

As an initial matter, the Court has some doubt about the methodology underlying Alcresta's loss calculation, which is based on an "estimate [by its marketing team] of . . . patients that would potentially benefit from the product." Oral Arg. Tr. at 17:14-16. Of course, many patients may benefit from products they ultimately do not procure and use, for myriad reasons. But even assuming that the company did lose $15.3 million in 2017, this economic injury is insufficient to establish irreparable harm. "'[T]he general rule' in this Circuit is 'that economic harm does not constitute irreparable injury.'" *Cardinal Health, Inc. v. Holder*, 846 F. Supp. 2d 203, 211 (D.D.C. 2012) (quoting *Davis v. Pension Ben. Guar. Corp.*, 571 F.3d 1288, 1295 (D.C. Cir. 2009)); *see also Wis. Gas Co.*, 758 F.2d at 674 ("It is also well settled that economic loss does not, in and of itself, constitute irreparable harm."). As another judge in this Circuit found in a case challenging Defendant's revocation of a company's Medicare billing privileges, "the sole fact that a company is losing money does not irreparable harm make." *Arriva Med. LLC v. HHS*, 239 F. Supp. 3d 266, 281 (D.D.C. 2017).

To be sure, courts have found that economic loss can constitute irreparable harm in certain limited circumstances. *See Cardinal Health*, 846 F. Supp. 2d at 211. But neither of them are present here. First, economic loss can constitute irreparable harm if it "threatens the very existence of the movant's business." *Wis. Gas Co.*, 758 F.2d at 674. Plaintiffs conceded at oral argument, however, that this is not one of those cases. *See* Oral Arg. Tr. at 19:2-12. Indeed, Plaintiffs did not provide any evidence situating Alcresta's alleged losses within the overall

financial health of the company. When asked about the company's overall financial situation, Plaintiffs merely provided an explanation of how they arrived at the $15.3 million figure. *See id.* at 17:5-23. But a $15.3 million loss, without more, is insufficient to establish a threat to the existence of Alcresta's business such that it could constitute irreparable harm. "[E]ven if [the plaintiff] is currently bleeding funds, it has neglected to provide basic accounting information in the form of a balance sheet showing its total assets and liabilities—which might reveal abundant cash reserves or other fungible assets." *Arriva Med. LLC*, 239 F. Supp. 3d at 281.

Second, courts have sometimes found irreparable harm where a claimed economic loss is "unrecoverable." *Cardinal Health*, 846 F. Supp. 2d at 211 (citing *Nat'l Mining Ass'n v. Jackson*, 768 F. Supp. 2d 34, 53 (D.D.C. 2011)). Plaintiffs rely on this argument, arguing that Alcresta's economic losses in this case are not recoverable because the APA does not permit money damages. *See* Pls.' PI Br. at 37-38. In support of their position, they cite district court cases from this Circuit holding that economic loss in an APA case constitutes per se irreparable injury where the loss is unrecoverable. *See id.* at 37 (citing *Smoking Everywhere, Inc. v. FDA*, 680 F. Supp. 2d 62, 77 n.19 (D.D.C. 2010) (in an APA case, "any loss of income suffered by [the] plaintiff is irreparable per se" (alteration in original)); *R.J. Reynolds Tobacco Co. v. FDA.*, 823 F. Supp. 2d 36, 50 (D.D.C. 2011) (applying *Smoking Everywhere* rule to find irreparable harm on the basis of "inability to recover costs from the FDA")); Pls.' Reply at 10 (citing *Nalco Co. v. EPA*, 786 F. Supp. 2d 177, 188 (D.D.C. 2011)).

The vast majority of district courts in this Circuit, however, have rejected the rule in *Smoking Everywhere* as overbroad. As one court persuasively explained, that rule "stretches too far. . . . [N]ot only is such a rule not the law of this Circuit, but it would also effectively eliminate the irreparable harm requirement. Any movant that could show any damages against

an agency with sovereign immunity—even as little as $1—would satisfy the standard." *Air Transp. Ass'n of Am., Inc. v. Exp.-Imp. Bank of the U.S.*, 840 F. Supp. 2d 327, 335 (D.D.C. 2012).

Instead, "[t]he wiser formula requires that the economic harm be significant, even where it is irretrievable." *Id.* This is the view adopted by the vast majority of opinions in this Circuit to address the issue. *See, e.g.*, *Save Jobs USA v. DHS*, 105 F. Supp. 3d 108, 115 (D.D.C. 2015) ("This court concurs with the reasoning in *Air Transport Association* and the other decisions in this District that unrecoverable economic losses do not automatically constitute irreparable harm, but instead must be sufficiently severe to warrant emergency relief."); *ConverDyn v. Moniz*, 68 F. Supp. 3d 34, 49 (D.D.C. 2014) ("While this Court previously characterized economic damages that are unrecoverable due to sovereign immunity as 'irreparable per se,' that characterization goes too far . . . ." (citations omitted)); *ViroPharma, Inc. v. Hamburg*, 898 F. Supp. 2d 1, 26 n.31 (D.D.C. 2012); *Nat'l Shooting Sports Found., Inc. v. Jones*, No. 11-cv-1401, 2011 WL 3875241, at *3 n.5 (D.D.C. Sept. 2, 2011) ("Taken out of context, the district court's statement [in *Smoking Everywhere*] that 'any loss of income' that cannot be recovered is irreparable is overbroad. The Circuit clearly requires that harm be both certain and great."); *N. Air Cargo v. USPS*, 756 F. Supp. 2d 116, 125 n.6 (D.D.C. 2010) ("While the Court agrees that irrecoverable financial loss may constitute irreparable injury in some cases, this Court is of the opinion that a party asserting such a loss is not relieved of its obligation to demonstrate that its harm will be 'great.' If this were not the case, then prospective injunctive relief would often cease to be an 'extraordinary remedy' in cases involving government defendants." (quoting *Winter*, 555 U.S. at 22)).

Alcresta has failed to establish that it is suffering irreparable injury that meets this standard. Whether the harm is "significant" can be evaluated only in the context of the movant's overall finances. *See Air Transp. Ass'n*, 840 F. Supp. 2d at 335-36; *Cardinal Health*, 846 F. Supp. 2d at 212-13. And even when prompted, *see* Oral Arg. Tr. at 17:5-23, Alcresta did not make any effort to situate its claimed losses in company's overall financial picture. Without this information, the Court cannot conclude that Alcresta's losses—even if irretrievable—rise to the level of irreparable harm.

Finally, courts in this Circuit have denied motions for preliminary injunctions when the alleged unrecoverable financial losses were significantly larger than what Plaintiffs allege in this case. *See, e.g.*, *Cardinal Health*, 846 F. Supp. 2d at 212-13 (loss of a billion dollars not irreparable harm where it was a small portion of the company's annual revenues); *Toxco Inc. v. Chu*, 724 F. Supp. 2d 16, 31 (D.D.C. 2010) ("[E]ven if the DOE's withdrawal did cause the plaintiff to lose the North Field project, the plaintiff has not shown that this economic loss, even if irretrievable and even when coupled with the losses resulting from the termination of the subcontract itself, is sufficiently severe so as to constitute irreparable harm."); *Sandoz, Inc. v. FDA*, 439 F. Supp. 2d 26, 32 (D.D.C. 2006) (holding that even if the court were to credit the plaintiff's claims of $31 million in irretrievably lost revenues, that loss was insufficiently severe in the context of the plaintiff's overall business operations to warrant a finding of irreparable harm), *aff'd*, No. 06-5204, 2006 WL 2591087 (D.C. Cir. Aug. 30, 2006). These cases further underscore that the sheer size of a company's unrecoverable loss, without the additional context within which it is suffered, does not demonstrate irreparable harm.

"A movant's failure to show any irreparable harm is . . . grounds for refusing to issue a preliminary injunction, even if the other three factors entering the calculus merit such relief."

Chaplaincy, 454 F.3d at 297. As such, "a court may refuse to issue an injunction without considering any other factors when irreparable harm is not demonstrated." *GEO Specialty Chemicals, Inc. v. Husisian*, 923 F. Supp. 2d 143, 147 & n.4 (D.D.C. 2013). Because Alcresta has failed to demonstrate irreparable harm, it is not entitled to a preliminary injunction.

B. Jonathan Flath

The Court finds that Flath has not demonstrated a substantial likelihood that he has standing, which is necessary to establish a likelihood of success on the merits. For similar reasons, he has also failed to demonstrate that he has suffered irreparable harm that will be addressed by the injunctive relief he seeks. As a result, he is also not entitled to a preliminary injunction.

1. Likelihood of Success on the Merits

a. Standing

"The doctrine of standing derives from Article III of the Constitution, which limits the jurisdiction of the federal courts to 'Cases' and 'Controversies.'" *Coal. for Mercury-Free Drugs v. Sebelius*, 671 F.3d 1275, 1278 (D.C. Cir. 2012) (quoting U.S. Const. art. III, § 2). "The standing requirements of Article III are . . . grounded in respect for the separation of powers tenets that are the foundation of our system of government . . . ." *Scenic Am., Inc. v. United States Dep't of Transp.*, 836 F.3d 42, 48 (D.C. Cir. 2016), *cert. denied* 138 S. Ct. 2 (2017). "Plaintiffs must satisfy constitutional standing requirements in order to invoke this Court's subject matter jurisdiction." *Cal. Clinical Lab. Ass'n v. Sec'y of HHS*, 104 F. Supp. 3d 66, 74 (D.D.C. 2015).

"[B]ecause 'standing is a necessary predicate to any exercise of [the Court's] jurisdiction, the [plaintiff] and [his] claims have no likelihood of success on the merits,' if the plaintiff lacks standing." *Arpaio v. Obama*, 27 F. Supp. 3d 185, 207 (D.D.C. 2014) (alterations

after first in original) (quoting *Smith v. Henderson*, 944 F. Supp. 2d 89, 99 (D.D.C. 2013)), *aff'd*, 797 F.3d 11 (D.C. Cir. 2015). To establish the "irreducible constitutional minimum of standing," a party "must have (1) an injury in fact, (2) fairly traceable to the challenged agency action, (3) that will likely be redressed by a favorable decision." *Kan. Corp. Comm'n v. FERC*, 881 F.3d 924, 929 (D.C. Cir. 2018) (citing *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992)). "[A] deficiency on any one of the three prongs suffices to defeat standing . . . ." *US Ecology, Inc. v. U.S. Dep't of Interior*, 231 F.3d 20, 24 (D.C. Cir. 2000). A plaintiff "bears the burden of showing that he has standing for each type of relief sought." *Summers v. Earth Island Inst.*, 555 U.S. 488, 493 (2009).

"In the context of a preliminary injunction motion, [the D.C. Circuit] require[s] the plaintiff to 'show a substantial likelihood of standing' 'under the heightened standard for evaluating a motion for summary judgment.'" *Elec. Privacy Info. Ctr. v. Presidential Advisory Comm'n on Election Integrity*, 878 F.3d 371, 377 (D.C. Cir. 2017) (quoting *Food & Water Watch, Inc. v. Vilsack*, 808 F.3d 905, 912-13 (D.C. Cir. 2015)) (internal quotation marks omitted). "Accordingly, to establish standing for a preliminary injunction, a plaintiff cannot 'rest on such mere allegations, [as would be appropriate at the pleading stage] but must set forth by affidavit or other evidence specific facts, which . . . will be taken to be true." *Food & Water Watch, Inc. v. Vilsack*, 79 F. Supp. 3d 174, 186 (D.D.C.) (alterations in original) (quoting *Lujan*, 504 U.S. at 561) (internal quotation marks omitted), *aff'd*, 808 F.3d 905 (D.C. Cir. 2015). "In assessing [plaintiffs'] standing, we must assume they will prevail on the merits of their claims." *Ams. for Safe Access v. DEA*, 706 F.3d 438, 443 (D.C. Cir. 2013) (quoting *NB ex rel. Peacock v. District of Columbia*, 682 F.3d 77, 82 (D.C. Cir. 2012)).

i. Injury-in-Fact

"An injury in fact is an 'invasion of a legally protected interest which is (a) concrete and particularized, and (b) actual or imminent, not conjectural or hypothetical.'" *Kan. Corp. Comm'n*, 881 F.3d at 929 (quoting *Lujan*, 504 U.S. at 560).

Here, Flath asserts that he has suffered injury to his health because Medicare or Medicaid will not guarantee full reimbursement for Relizorb, which provided him significant health benefits during the three months he was provided it. *See, e.g.*, Flath Decl. ¶¶ 31-46; Pls.' Reply at 4 ("The uncontested, detailed showing of irreparable injury to Mr. Flath alone is sufficient to establish . . . standing . . . ."); *id.* at 3 ("Plaintiffs' sworn declarations supporting irreparable harm plainly demonstrate standing."); Pls.' Supp. Br. at 19-20. The Court assumes that this alleged injury is sufficient to establish injury-in-fact for the purposes of standing. *See, e.g.*, *Carik v. HHS*, 4 F. Supp. 3d 41, 52 (D.D.C. 2013) (plaintiff that alleged her eyesight was failing and would soon be lost entirely without treatment demonstrated injury-in-fact because "[t]his is the sort of harm necessary to show the particularized, concrete, imminent injury required for Article III standing"); *Pub. Citizen, Inc. v. Nat'l Highway Traffic Safety Admin.*, 489 F.3d 1279, 1292 (D.C. Cir. 2007) (finding "physical injuries" from car accidents are "plainly concrete harms under the Supreme Court's precedents").

ii. Redressability

Flath's argument founders, however, at both the redressability and causation prongs of standing. "Redressability examines whether the relief sought, assuming that the court chooses to grant it, will likely alleviate the particularized injury alleged by the plaintiff." *Fla. Audubon Soc'y v. Bentsen*, 94 F.3d 658, 663-64 (D.C. Cir. 1996) (en banc) (footnote omitted). "Relief that does not remedy the injury suffered cannot bootstrap a plaintiff into federal court . . . ." *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 107 (1998).

The Court concludes that Flath has failed to show that the relief sought will likely redress his injury. Plaintiffs' Amended Complaint requests, among other things, that the Court set aside Defendant's decision on Alcresta's 2017 application, declare that the Workgroup violated FACA, direct the agency to use "proper administrative procedures" in considering Alcresta's 2018 application, and provide a temporary new billing code for Relizorb. *See* Am. Compl. at 50-51. Therefore, to demonstrate redressability for Flath, Plaintiffs must show that it is likely that if the Court ordered this relief—in particular, a unique billing code for Relizorb—that Relizorb would be fully reimbursed (or at least, reimbursed to such a degree that he can afford to pay for any remaining amount). They have failed to do so.

As already described, Defendant does not provide full reimbursement for Relizorb under Medicare, for which Flath is eligible. *See* Flath Decl. ¶ 40. Plaintiffs argue, however, that a new billing code for Relizorb would change that: "[f]or a newly coded product that is not yet on the national fee schedule, the Medicare contractors are required to set a payment amount based on a predetermined methodology reflecting suppliers' charges for the product and local pricing factors." Pls.' Supp. Br. at 15. But as Defendant points out in an unrebutted and sworn declaration, this "argument reflects a misunderstanding of Medicare payment policy and, more importantly, how HCPCS codes are used." Wilson Decl. ¶ 10. Specifically, "[t]he policy and methodology referred to by Plaintiffs does not apply to the circumstances of this case, where the agency has previously established specific Medicare rules" that "provide for an all-inclusive daily fee schedule payment for enteral nutrition supplies and do not provide for a separate payment for individual enteral supplies, regardless of the establishment of a code identifying an individual enteral supply." *Id.* Thus, according to Defendant, under the rules in place, "the existence of a new code identifying an individual enteral supply does not mean that the supply

would qualify for additional Medicare payment beyond the all-inclusive payment." *Id.* ¶ 9. The distinction between billing codes and reimbursement is buttressed by the HCPCS Code Book, which states that "[i]nclusion or exclusion of a procedure, supply, product or service [in a billing code] does not imply any health insurance coverage or reimbursement policy." ECF No. 12-1 at 3. And in Plaintiffs' Motion, they originally appeared to have all but conceded this point, at least as far as Medicare and Medicaid are concerned, arguing that "the government faces no financial harm, as the coding decision for a product is separate from a decision on the level of government health care programs' reimbursement for it." Pls.' PI Br. at 2.

Events during the pendency of this case further undermine Plaintiffs' argument that a unique billing code for Relizorb would redress Flath's injury. Defendant *already provided* a temporary unique billing code for Relizorb, but nonetheless appended indicators to it that made clear that the new code could not be used to obtain any additional reimbursement beyond the existing all-inclusive daily allowance for enteral therapy under Medicare. So there is no reason to believe it is likely that Defendant's provision of yet *another* unique billing code would bring about Relizorb's full reimbursement under Medicare for Flath. Again, the declaration submitted by Defendant makes clear that "the agency has previously established specific Medicare rules directing how to treat . . . enteral nutrition supplies . . . , regardless of the establishment of a code identifying an individual enteral supply." Wilson Decl. ¶ 10.

In addition to Medicare, Flath is also eligible for Medicaid in Minnesota. Pls.' Reply at 5; *see* Flath Decl. ¶¶ 2, 40. But according to Plaintiffs, "because Minnesota's Medicaid program uses assigned HCPCS codes and follows Medicare coverage guidelines, the result is the same under Medicaid." Pls.' Supp. Br. at 19; *see also* Pls.' Reply at 5 & n.1; Flath Decl. ¶ 43. Thus, since Plaintiffs have not established that the relief sought would bring about Medicare's full

reimbursement for Relizorb, thereby redressing Flath's injury, neither have they done so for Medicaid. In fact, Plaintiffs have not even attempted to argue how a permanent unique billing code for Relizorb would induce the administrators of Minnesota's Medicaid program to provide reimbursement for Relizorb. *See Nat'l Wrestling Coaches Ass'n v. Dep't of Educ.*, 366 F.3d 930, 938 (D.C. Cir. 2004) ("[T]he Supreme Court has made clear that a plaintiff's standing fails where it is purely speculative that a requested change in government policy will alter the behavior of . . . third parties that are the direct cause of the plaintiff's injuries."), *abrogated on other grounds as stated in Perry Capital LLC v. Mnuchin*, 864 F.3d 591, 620-21 (D.C. Cir. 2017). And while Plaintiffs offer some evidence that non-governmental insurers are reluctant to provide reimbursement for Relizorb because it lacks a unique billing code, Gamgort Decl. ¶¶ 11-12, 19, these insurers are irrelevant to Flath's predicament, because he does not rely on private insurance. Thus, for all the above reasons, Flath has failed to demonstrate that his alleged injury will be redressed by the relief sought.

iii. Causation

Flath fares no better on causation. "It is well established that '[c]ausation, or "traceability," examines whether it is substantially probable that the challenged acts of the defendant . . . will cause the particularized injury of the plaintiff.'" *Grocery Mfrs. Ass'n v. EPA*, 693 F.3d 169, 176 (D.C. Cir. 2012) (quoting *Fla. Audubon Soc'y*, 94 F.3d at 663).

For all the reasons discussed above relating to redressability, the Court concludes that Flath also has not shown that it is substantially probable that his injury was caused by Defendant's challenged act—namely, its rejection of Alcresta's request for a permanent unique billing code. Once again, Flath's injury was caused by the fact that Medicare and Medicaid, for

which he is eligible, do not provide full reimbursement for Relizorb.[4] *See* Flath Decl. ¶ 40. And Flath has not demonstrated that these reimbursement determinations were caused by Defendant's decision to deny Relizorb a unique billing code.[5]

In light of all of the above, Plaintiffs have failed to establish that there is a substantial likelihood that Flath has standing, which is a predicate for establishing a likelihood of success on the merits. The Court must deny his request for a preliminary injunction on this basis alone. *See, e.g.*, *Newdow v. Bush*, 355 F. Supp. 2d 265, 282 (D.D.C. 2005) (denying preliminary

[4] Plaintiffs also assert that they have alleged a procedural injury—violation of FACA—that confers standing to sue. Pls.' Reply at 11-12. But while a statutory procedural violation could, in theory, assist Flath in showing redressability, it cannot help him to establish causation (*i.e.*, traceability). *See, e.g.*, *Nat'l Ass'n of Home Builders v. EPA*, 667 F.3d 6, 15 (D.C. Cir. 2011) ("'Unlike redressability, however, the requirement of injury in fact is a hard floor of Article III jurisdiction that cannot be removed by statute.' Without an imminent threat of injury traceable to the challenged action, that floor stands as a ceiling." (citation omitted) (quoting *Summers*, 555 U.S. at 497)); *Renal Physicians Ass'n v. HHS*, 489 F.3d 1267, 1279 (D.C. Cir. 2007) ("[T]hough the plaintiff in a procedural-injury case is relieved of having to show that proper procedures would have caused the agency to take a different substantive action, the plaintiff must still show that the agency action was the cause of some redressable injury to the plaintiff."); *Ctr. for Law & Educ. v. Dep't of Educ.*, 396 F.3d 1152, 1160 (D.C. Cir. 2005) ("Appellants must still demonstrate a causal relationship between the final agency action and the alleged injuries."). Here, Flath's injury—most directly caused by his inability to procure Relizorb—is too attenuated from the alleged FACA violations to satisfy the traceability requirement.

[5] "When a plaintiff's asserted injury arises from the Government's regulation of a third party that is not before the court, it becomes 'substantially more difficult' to establish standing." *Nat'l Wrestling*, 366 F.3d at 938 (quoting *Lujan*, 504 U.S. at 562). "[I]t becomes the burden of the plaintiff to adduce facts showing that those choices [of a third party] have been or will be made in such manner as to produce causation." *Id.* (quoting *Lujan*, 504 U.S. at 562). Here, Plaintiffs have not even attempted to show a causal relationship between Defendant's decisions on Relizorb's billing code and any decisions by the Minnesota Medicaid program not to fully reimburse for Relizorb. As a result, they have fallen far short of "adduc[ing] facts," *id.* (quoting *Lujan*, 504 U.S. at 562), demonstrating that Defendant's billing code decisions were "at least a substantial factor" motivating any decisions of the administrators of the Minnesota Medicaid program, *Tozzi v. HHS*, 271 F.3d 301, 308 (D.C. Cir. 2001) (quoting *Cmty. for Creative Non-Violence v. Pierce*, 814 F.2d 663, 669 (D.C. Cir. 1987)).

injunction because "[w]ithout . . . standing, [plaintiff] would be unable to succeed on the merits of his claims").

2. Irreparable Harm

Turning to irreparable harm, plaintiffs seeking preliminary relief must "demonstrate that irreparable injury is *likely* in the absence of an injunction." *Winter*, 555 U.S. at 22. And "the movant must show that the alleged harm will directly result from the action which the movant seeks to enjoin." *Wis. Gas Co.*, 758 F.2d at 674; *see also Navistar, Inc. v. EPA*, No. 11-cv-449, 2011 WL 3743732, at *2 (D.D.C. Aug. 25, 2011) ("In order to meet its burden of proving irreparable injury, [plaintiff] 'must demonstrate a causal connection between the alleged harm and the actions to be enjoined; a preliminary injunction will not issue unless it will remedy the alleged injuries.'" (quoting *Hunter Grp., Inc. v. Smith*, No. 97-2218, 1998 WL 682154, at *2 (4th Cir. Sept. 23, 1998)). Indeed, "[i]t would make little sense for a court to conclude that a plaintiff has shown irreparable harm when the relief sought would not actually remedy that harm. A plaintiff may be irreparably harmed by all sorts of things, but the irreparable harm considered by the court must be caused by the conduct in dispute and remedied by the relief sought." *Sierra Club v. DOE*, 825 F. Supp. 2d 142, 153 (D.D.C. 2011).

Plaintiffs argue that Flath is suffering irreparable harm because he is unable to procure and use Relizorb, which benefited his health during the three months he used it. *See* Pls.' Reply at 3-4. But even assuming that the alleged effect of Flath's inability to access Relizorb on his health is an injury that could form the basis for a claim of irreparable harm, "the same problem that confronts the plaintiff's standing argument—the inability to obtain redress from an order by this Court—likewise dooms the plaintiff's ability to show irreparable harm." *Arpaio*, 27 F. Supp. 3d at 207. To purportedly remedy Flath's harm, Plaintiffs request that Defendant issue a new temporary code for Relizorb; revisit its decision on Alcresta's 2017 application; and

"[a]dhere to proper administrative procedure" in considering Alcresta's 2018 application. PI Mot. But again, for all the reasons already explained, Plaintiffs have not shown that this injunctive relief will cause Medicare or Medicaid to provide any additional reimbursement for Relizorb, thereby remedying Flath's injury.

Thus, because Flath has failed to demonstrate that "the alleged harm will directly result from the action which the movant seeks to enjoin," *Wis. Gas Co.*, 758 F.2d at 674, he has not established irreparable harm. *See, e.g.*, *Cayuga Nation v. Zinke*, No. 17-cv-1923, 2018 WL 1515239, at *7 (D.D.C. Mar. 27, 2018) (denying preliminary injunction because there was a "disconnect" between injuries asserted and the relief requested, which would not prevent those injuries from occurring); *Navistar*, 2011 WL 3743732, at *3 ("Because an injunction will not redress its alleged injuries, [plaintiff's] claim that it will suffer irreparable harm in the absence of a preliminary injunction is tenuous at best."). Failure to demonstrate any irreparable harm is a separate and independent reason why the Court must deny his request for a preliminary injunction. *GEO Specialty Chemicals,* 923 F. Supp. 2d at 147 & n.4.

As noted earlier, Plaintiffs' ultimate goal does not appear to be to obtain a unique billing code for Relizorb, but to get insurers—including Medicare—to provide full reimbursement for it. But regardless of the merits of either of these matters, for the reasons described above, Plaintiffs have not demonstrated that they are entitled to a preliminary injunction on the record before the Court. To the extent that Flath seeks to challenge the fact that his insurers do not provide full reimbursement for Relizorb, he may contest those determinations as provided by law. In the case of Medicare, for instance, such determinations are governed by a separate statutory scheme that does not provide this Court jurisdiction until he exhausts his administrative remedies, 42 U.S.C. § 405(g)-(h); *Am. Orthotic & Prosthetic Ass'n v. Sebelius*, 62 F. Supp. 3d 114, 122

(D.D.C. 2014); *see also* Wilson Decl. ¶¶ 15-16. But unfortunately for him, this lawsuit cannot be his means to do so.

IV. Conclusion

For all of the above reasons, Plaintiffs' Motion for Preliminary Injunction, ECF No. 8, is **DENIED**.

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

Date: June 15, 2018