UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

MALLINCKRODT ARD LLC, Plaintiff, v. SEEMA VERMA, *et al.*, Defendants.	Civil Action No. 19-cv-1471 (TFH)

MEMORANDUM OPINION

Pending before the Court is plaintiff Mallinckrodt ARD LLC's (Mallinckrodt's) Emergency Motion for Reconsideration and Stay of Entry of Judgment Pending Reconsideration or, Alternatively, Injunction Pending Appeal, ECF No. 37. Mallinckrodt invokes Rules 59, 60, and 62(c) of the Federal Rules of Civil Procedure, along with Rule 8(a)(1) of the Federal Rules of Appellate Procedure, to request that the Court do the following three things: (1) reconsider its March 13, 2020, memorandum opinion granting summary judgment in favor of defendants Seema Verma, Administrator of the Centers for Medicare & Medicaid Services (CMS), and Alex M. Azar II, Secretary of the United States Department of Health and Human Services (HHS); (2) stay the entry of judgment pending reconsideration; and (3) issue an injunction prohibiting CMS from "locking" Mallinckrodt out of the Drug Data Reporting for Medicaid (DDR) system or otherwise enforcing the judgment before Mallinckrodt can litigate an appeal. Mem. of P. & A. in Support of Pl.'s Emergency Mot. 1, ECF No. 37-1 (hereinafter cited as "Mallinckrodt's Br."). Mallinckrodt contends that these judicial actions are warranted because the Court "fundamental[ly] misread[]" the controlling statute and the company faces an "existential threat"

of financial ruin if CMS locks the company out of the Drug Data Reporting for Medicaid system before an appeal is resolved. Mallinckrodt's Br. 3. The defendants oppose the motion.

Because the Court holds that Mallinckrodt failed to carry its burden of establishing that reconsideration is appropriate, that it is likely to succeed on the merits of an appeal, or that it is likely to be irreparably harmed absent a stay pending appeal, the Court will deny Mallinckrodt's motion for the reasons that follow.

DISCUSSION[1]

I. MALLINCKRODT FAILED TO ESTABLISH THAT RECONSIDERATION IS WARRANTED

Mallinckrodt's motion is titled as one for "reconsideration" but, aside from vague first-paragraph citations to Rules 59 and 60 of the Federal Rules of Civil Procedure, Mallinckrodt never identifies the relevant provisions of these rules that it believes authorize reconsideration, the legal standards associated with those provisions, or how it believes it has satisfied those standards. *See* Mallinckrodt's Mot. 1; Mallinckrodt's Br. 1, 3–12; Mallinckrodt's Reply Br. 1–10, ECF No. 41. Because Mallinckrodt failed to specify the relevant provisions of the rules that it is relying on, the Court is left to assume that they are Rule 59's subparagraph (e) and Rule 60's subparagraph (b), although it is unclear which of subparagraph (b)'s enumerated provisions Mallinckrodt is advancing. Regardless, reconsideration under either Rule 59(e) or Rule 60(b) is considered "extraordinary" and unwarranted when a litigant simply recycles legal arguments that were previously considered and rejected by a court, as is the case here. *See, e.g.*, *Leidos, Inc. v. Hellenic Republic*, 881 F.3d 213, 217 (D.C. Cir. 2018) (stating that reconsideration under Rule 59(e) is an "extraordinary measure" that cannot be used to reargue matters a court already

[1] This opinion assumes that the reader is familiar with the facts of the case, which are discussed at length in the Court's March 13, 2020, memorandum opinion. *See* Mem. Op., ECF No. 35.

considered); *Kramer v. Gates*, 481 F.3d 788, 790 (D.C. Cir. 2007) ("[R]elief under Rule 60(b)(6) is appropriate only in 'extraordinary circumstances.'" (quoting *Ackermann v. United States*, 340 U.S. 193, 199 (1950))); *Howard v. U.S. Dep't of Educ.*, 756 F. Supp. 2d 72, 74 (D.D.C. 2010) (rejecting reconsideration under Rule 60(b) when a plaintiff "rehash[ed] the same argument" made in a prior motion).

A. Rule 59(e) of the Federal Rules of Civil Procedure

Addressing Rule 59(e) first, this rule permits a court to exercise the discretion to alter or amend a judgment when (1) the controlling law has changed, (2) new evidence has become available, or (3) the court needs to correct a clear error or prevent manifest injustice. *Firestone v. Firestone*, 76 F.3d 1205, 1208 (D.C. Cir. 1996) (per curiam); Fed. R. Civ. P. 59(e). Absent one of these three circumstances, though, "[a] district court need not grant a Rule 59(e) motion." *Mohammadi v. Islamic Republic of Iran*, 782 F.3d 9, 17 (D.C. Cir. 2015). And it is well established that the rule is not available to "relitigate old matters." *Exxon Shipping Co. v. Baker*, 554 U.S. 471, 486 (2008) (quoting 11 C. Wright & A. Miller, Federal Practice and Procedure § 2810.1, pp. 127–128 (2d ed.1995)).

As the Court already noted, absent from Mallinckrodt's motion and supporting legal briefs is any discussion about the legal standards that apply to a Rule 59(e) motion or how Mallinckrodt believes that it has satisfied them. *See* Mallinckrodt's Mot.; Mallinckrodt's Br.; Mallinckrodt's Reply Br., ECF No. 41. Mallinckrodt offers nothing in the way of an argument hinting at the possibility that the controlling law has changed or that new evidence is available. Moreover, a word search of Mallinckrodt's motion, supporting legal brief, and reply brief reveals that the terms "clear error" and "manifest injustice" are nowhere to be found. *See id.*

At best, Mallinckrodt argues that the Court's "construction of the [Medicaid Drug Rebate Program] statute as focusing on whether the drug is 'an entirely new drug' is simply unfounded" therefore "[r]econsideration should be granted in order to permit the Court to engage again with the relevant statutory language, with the parties' briefs, and with the transcript of the August 2, 2019 argument on this critical point of statutory interpretation." Mallinckrodt's Mot. 9. But the Court's opinion never focused on whether Acthar was an entirely new drug. Instead, it focused on what the statute actually says, which is that the base date Average Manufacturer Price (AMP) is set on the date the "covered outpatient drug" was "approved by" the United States Food and Drug Administration (FDA) and "first marketed." Mem. Op. 35–37, ECF No. 35.

The statute plainly does not contemplate that a covered outpatient drug's base date AMP can be "reset" later during that drug's lifecycle, as CMS correctly cautioned Mallinckrodt in 2012, A.R. 617, absent, perhaps, FDA-approved new dosage forms or strengths, *see* 42 U.S.C. § 1396r-8(c)(2), which are not at issue here. And fatal to Mallinckrodt's case are its concessions that (1) the covered outpatient drug H.P. Acthar Gel® was "approved by" the FDA in 1952 under New Drug Application (NDA) number 008372 and (2) the only things the FDA approved under defunct NDA number 022432 were the addition of an infantile spasm indication along with other label revisions to a "decades-old drug."[2] Verified Compl. ¶ 27, ECF No. 1;

[2] Paragraphs 29 and 30 of Mallinckrodt's Verified Complaint summarize the very facts that reveal as a charade Mallinckrodt's contention that the FDA approved a "distinct"—i.e., new—drug under NDA 022432:

> Questcor acquired H.P. Acthar Gel in 2001, and in 2006 sought to have the product approved for the treatment of IS. The request for approval, which presented information and data from published literature on the use of H.P. Acthar Gel for IS, was submitted as a supplement to the existing NDA (sNDA). In May 2007, FDA issued what is now called a "Complete Response Letter" (CRL), in which the agency declined to approve Questcor's sNDA, explaining that the company had not

Mallinckrodt's Reply Br. 5 (admitting that what the FDA approved in 2010 were label revisions for a "decades-old drug product," including adding an infantile spasm indication).

Divested of its reliance on sheer insistence, Mallinckrodt's argument amounts to a bald disagreement with the outcome that fails to establish, or even present, a clear error or manifest injustice, neither of which can be "demonstrated by the disappointment of the losing party." *Oto v. Metro. Life Ins. Co.*, 224 F.3d 601, 606 (7th Cir. 2000). Upon careful consideration of Mallinckrodt's motion and supporting legal briefs, it is clear to the Court that the company

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> shown a sufficient nexus between the product and the relied-upon studies to meet the standards for approval.
>
> Consistent with FDA procedure, *the sNDA remained pending* while Questcor and FDA reached agreement on how to address the asserted inadequacy, and the company set about developing the necessary data. During this period, FDA unilaterally *converted the sNDA* to a new, separate NDA, to which (consistent with standard procedures) the agency assigned a distinct NDA number: NDA 022432. The agency took this action because it concluded the IS indication was fundamentally different from the *other uses* for which *the product had been approved*, and *required review by a different component within FDA* than had to date been responsible for the drug. The new NDA was classified as a "Type 6" NDA, *which was used for drug products that had already been approved or marketed by the same applicant, but were intended for a new indication or claim*.

Verified Comp. ¶¶ 29, 30 (emphases added). These paragraphs serve as an express admission that no distinct "drug" was "approved by" the FDA under defunct provisional NDA number 022432; rather, NDA number 022432 served solely as a ministerial (and temporary) mechanism for the FDA to facilitate another division reviewing what Mallinckrodt does not dispute was, in fact, "a supplement to the existing NDA"—i.e., NDA number 008372. More to the point, Mallinckrodt admits that NDA number 022432 involved a "drug product" that "had already been approved or marketed" but was "intended for a new indication or claim," Verified Compl. ¶ 30, which means that there was no new (or, as Mallinckrodt seeks to characterize it, "distinct") drug that could qualify as a separate "covered outpatient drug . . . approved by" the FDA after October 1, 1990 for the purpose of resetting the base date AMP pursuant to 42 U.S.C. § 1396r-8(c)(2)(A)(ii)(II), as amended by 42 U.S.C. § 1396r-8(c)(2)(B), *see infra* Part II(A). There is no mistaking that the statute expressly requires that the FDA "approval" be of a "covered outpatient drug" under 42 U.S.C. § 1396r-8(c)(2)(A)(ii)(II) and not simply be "approval" of an NDA, as Mallinckrodt urges.

"merely [takes] umbrage with the court's ruling and rehashe[s] old arguments" without ever establishing a legal basis for reconsideration under Rule 59(e). *Id.* As a result, Mallinckrodt failed to carry its burden of demonstrating that reconsideration is warranted under that rule. *See, e.g.*, *Schoenman v. F.B.I.*, 857 F. Supp. 2d 76, 80 (D.D.C. 2012) (stating that "[m]otions under Rule 59(e) are disfavored and the moving party bears the burden of establishing extraordinary circumstances warranting relief from a final judgment" (internal quotation marks omitted)); *Niedermeier v. Office of Baucus*, 153 F. Supp. 2d 23, 28 (D.D.C. 2001) (same).

B. Rule 60(b) of the Federal Rules of Civil Procedure

Turning to Rule 60(b), this rule is "intended to preserve the delicate balance between the sanctity of final judgments . . . and the incessant command of the court's conscience that justice be done in light of all the facts." *Good Luck Nursing Home, Inc. v. Harris*, 636 F.2d 572, 577 (D.C. Cir. 1980) (quotation marks omitted). Rule 60(b) sets forth six grounds upon which a litigant may obtain relief from a final judgment, order, or proceeding, only two of which are potentially relevant here. The first ground is Rule 60(b)(1), which provides that the court may relieve a litigant from a final judgment, order, or proceeding for "mistake, inadvertence, surprise, or excusable neglect." Fed. R. Civ. P. 60(b)(1). The second ground is Rule 60(b)(6), which allows the Court to relieve a litigant from a final judgment, order, or proceeding for "any other reason that justifies relief." Rule 60(b)(6). Mallinckrodt again neglects to identify which ground it is invoking to seek relief and fails to argue—much less establish—that relief is warranted under either.

Notwithstanding that Rule 60(b) "grants federal courts broad authority to relieve a party from a final judgment upon such terms as are just," *Liljeberg v. Health Services Acquisition Corp.*, 486 U.S. 847, 863 (1988), a litigant nevertheless "must clear a very high bar" to secure

this relief, *Kramer*, 481 F.3d at 792. With respect to Rule 60(b)(1), relief resulting from mistake, inadvertence, surprise, or excusable neglect is "rare" because district courts are permitted to "correct only limited types of substantive errors." *Hall v. C.I.A.*, 437 F.3d 94, 99 (D.C. Cir. 2006). And as far as Rule 60(b)(6) is concerned, relief under that provision "is even more rare, being available only in 'extraordinary circumstances.'" *Owens v. Republic of Sudan*, 864 F.3d 751, 818 (D.C. Cir. 2017), *certified question answered*, 194 A.3d 38 (D.C. App. 2018) (quoting *Ackermann v. United States*, 340 U.S. 193, 199 (1950)). Furthermore, the United States Court of Appeals for the District of Columbia Circuit has noted that "a dispute over the proper interpretation of a statute, by itself, does not likely justify relief under Rule 60(b)(6)." *Id.* at 818 n.11. Precedent also "makes clear that Rule 60(b)(6) is not an opportunity for unsuccessful litigants to take a mulligan," *Kramer*, 481 F.3d at 792, nor can it serve to "rescue a litigant from strategic choices that later turn out to be improvident," *Good Luck Nursing Home, Inc.*, 636 F.2d at 577.

Faced with insufficient legal arguments from which the Court can discern (1) which Rule 60(b) provisions Mallinckrodt is invoking and (2) whether relief is warranted under any such provisions, the Court is deprived of any legal basis to grant the requested reconsideration.

C. Summary Conclusion

Whether Mallinckrodt intended to lend an air of mystery to its motion or to obfuscate an argument it viewed as weak, the fact of the matter is that, as the Seventh Circuit aptly observed nearly three decades ago, "[j]udges are not like pigs, hunting for truffles buried in briefs." *United States v. Dunkel*, 927 F.2d 955, 956 (7th Cir. 1991). The Court is not obligated to divine from Mallinckrodt's briefs a viable legal argument that it failed to adequately present. To the contrary, the burden to demonstrate that reconsideration is warranted under either Rule 59 or

Rule 60 belongs to Mallinckrodt. *See, e.g.*, *Schoenman*, 857 F. Supp. 2d at 80; *Niedermeier*, 153 F. Supp. 2d at 28; *Owens*, 864 F.3d at 819.

Because Mallinckrodt failed to provide any legal discussion about how or why Rules 59 and 60 apply, it failed to carry its burden of supplying the "extraordinary" circumstances that justify relief under either rule and, in any event, reconsideration is not available to reargue grounds the Court already considered and found unconvincing. *See, e.g.*, *Leidos*, 881 F.3d at 217; *Kramer*, 481 F.3d at 790; *Howard*, 756 F. Supp. 2d at 74. For all the foregoing reasons, the Court will decline Mallinckrodt's invitation to exercise judicial discretion by granting reconsideration under either rule. Mallinckrodt's motion for reconsideration will therefore be denied.

II. A STAY PENDING APPEAL IS NOT WARRANTED

In addition to reconsideration, Mallinckrodt also seeks to stay the entry of judgment pending reconsideration and enjoin the defendants from "locking" the company out of the federal database that governs Medicaid rebates until the company can resolve an appeal of the Court's March 13, 2020, decision granting summary judgment in the defendants' favor. Mallinckrodt's Mot. 1. On May 8, 2020, the parties filed a Joint Notice of Parties, ECF No. 45, which advised the Court that the defendants "agreed to refrain from locking Mallinckrodt out of CMS's online data reporting system until June 14, 2020." The Court commends the parties for collaborating to reach this intermediate resolution without the need for judicial intervention. Although the parties' agreement and this opinion appear to moot Mallinckrodt's requested stay of the Court's judgment pending reconsideration, *see, e.g.*, *Reporters Comm. for Freedom of Press v. Sampson*, 591 F.2d 944, 950 (D.C. Cir. 1978) ("[A]n issue is moot if it has lost its character as a present, live controversy."), Mallinckrodt's request for an injunction to prevent the defendants from locking the company out of the database pending the resolution of an appeal remains a live issue.

Mallinckrodt asserts that it is entitled to an injunction because it is likely to succeed on the merits of an appeal and would suffer irreparable harm if during an appeal it is unable to report or revise Acthar's drug pricing in the Drug Data Reporting for Medicaid database, it is subjected to civil monetary penalties, and its National Drug Rebate Agreement (NDRA) is suspended.[3] Mallinckrodt's Mot. 13. The defendants counter by arguing that, among other points, "a stay would inflict immense harm upon the Government and the public," Gov't's Opp'n Br. 4, "equity clearly tips against permitting Mallinckrodt to continue course by withholding payment pending appeal to the detriment of the Medicaid Program," *id.* at 4–5, and the "magnitude of the harm to the Government and public is severe and continuing to grow" given that "Mallinckrodt has effectively retained an interest-free loan at taxpayers' expense to date—indeed, CMS may never be able to recover interest on Mallinckrodt's past underpayment," *id.* at 5. The defendants also challenge Mallinckrodt's claim that if an injunction is not granted Mallinckrodt's immediate liability for approximately $600 million in Medicaid rebate underpayments would threaten the company's existence, *id.* at 6, particularly when the company recently stated that 2019 was a successful year, *id.* at 6–7.

As an initial matter, Mallinckrodt's request to prohibit CMS from "altering the status quo by locking [Mallinckrodt] out of the Drug Data Reporting for Medicaid (DDR) system or taking any other enforcement action pending appeal" is presented as an "alternative" request for an

[3] Mallinckrodt argues that "because it is the NDRA that is the condition precedent to states' obligation to cover a manufacturer's covered outpatient drugs, when Mallinckrodt's NDRA is suspended, states will no longer be required to cover Mallinckrodt's covered outpatient drugs, including Acthar." Mallinckrodt's Mot. 13. The irony of this argument cannot elude Mallinckrodt in light of its veiled threat to quit the Medicaid Drug Rebate Program in 2012. *See* A.R. 142 (insinuating that Acthar's ongoing participation in the program might be "untenable" if CMS refused to reduce its rebate liability but that its departure was not "in the interest of CMS, as we believe state Medicaid programs likely still will be required to cover Acthar's use for infantile spasms even if Questcor does exit the program").

"injunction." Mallinckrodt's Mot. 1. Mallinckrodt cites, however, Rule 62 of the Federal Rules of Civil Procedure, which governs "stays" of judicial proceedings. Although an injunction "has some functional overlap" with a stay pending appeal, the Supreme Court's decision in *Nken v. Holder*, 556 U.S. 418, 429 (2009), indicates that, in circumstances like this one where the moving party is asking the Court to maintain the status quo by suspending the opposing party's authority to act—i.e., by suspending the Court's March opinion and judgment—the appropriate remedy is a stay, albeit the same legal standards apply to stays pending appeal and injunctions, *see Washington Metro. Area Transit Comm'n v. Holiday Tours, Inc.*, 559 F.2d 841, 842 n.1 (D.C. Cir. 1977) (noting that the factors to establish the stay of the administrative order at issue in *Virginia Petroleum Jobbers Ass'n v. Fed. Power Comm'n*, 259 F.2d 921 (D.C. Cir. 1958), "also apply to motions for preliminary injunctions and motions for stays of district court orders pending appeal").

The D.C. Circuit has characterized the legal standards to obtain a stay as "stringent"[4] and identified the following four factors as determinative:

> (1) Has the petitioner made a strong showing that it is likely to prevail on the merits of its appeal? Without such a substantial indication of probable success, there would be no justification for the court's intrusion into the ordinary processes of administration and judicial review. (2) Has the petitioner shown that without such relief, it will be irreparably injured? . . . (3) Would the issuance of a stay substantially harm other parties interested in the proceedings? . . . (4) Where lies the public interest?

Washington Metro. Area Transit Comm'n, 559 F.2d at 842–43 (quoting *Virginia Petroleum Jobbers Ass'n*, 259 F.2d at 925). Historically, courts in this jurisdiction applied a so-called

[4] *See, e.g.*, *Advanta Bank v. F.D.I.C.*, No. 10-5051, 2010 WL 1050253, at *1 (D.C. Cir. Mar. 11, 2010) (per curiam) (referring to the "stringent standards required for a stay pending appeal"); *Kiyemba v. Bush*, No. 08-5424, 2008 WL 4898963, at *1 (D.C. Cir. Oct. 20, 2008) (per curiam) (same); *Al-Bandar v. Bush*, No. 06 5425, 2006 WL 3986241, at *1 (D.C. Cir. Dec. 29, 2006) (per curiam) (same).

"sliding scale" analysis to these factors whereby "a strong showing on one factor could make up for a weaker showing on another." *Sherley v. Sebelius*, 644 F.3d 388, 392 (D.C. Cir. 2011). After the Supreme Court's decision in *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7 (2008), however, the D.C. Circuit questioned this approach on the ground that "*Winter* could be read to create a more demanding burden than the sliding-scale analysis requires." *Sherley*, 644 F.3d at 392 (internal quotation marks omitted). The D.C. Circuit has not yet decided, however, whether *Winter* requires that the sliding scale approach be "abandoned." *Archdiocese of Washington v. Washington Metro. Area Transit Auth.*, 897 F.3d 314, 334 (D.C. Cir. 2018), *cert. denied*, 140 S. Ct. 1198 (2020). At a minimum, though, the D.C. Circuit has stated that it "read[s] *Winter* at least to suggest if not to hold that a likelihood of success is an independent, free-standing requirement for a preliminary injunction." *Id.* at 393.

Indeed, the Supreme Court made clear in *Winter* that a movant must establish that it is "likely" *both* that he will succeed on the merits *and* that irreparable harm will follow if the requested stay is withheld. 555 U.S. at 21–22. The Supreme Court rejected as "too lenient" a standard according to which a movant who makes a "strong" showing that success on the merits is "likely" would then be permitted to make a lesser showing that irreparable harm is merely "possible." *Id.* at 22; *see also id.* at 20 (stating that "[a] plaintiff seeking a preliminary injunction must establish that the is likely to succeed on the merits" *and* "that he is likely to suffer irreparable harm," as well as "that the balance of equities tips in his favor" and "that an injunction is in the public interest"). Because the movant must demonstrate both of these factors to a degree of probability characterized as "likely," there appears to be no room for the Court to assess that a more robust showing of one opens the door to a lesser showing of the other, at least to the extent that the lesser showing is something that falls below "likely." *See Davis v. Pension*

Ben. Guar. Corp., 571 F.3d 1288, 1296 (D.C. Cir. 2009) (Kavanaugh, J., concurring) ("Importantly, the *Winter* Court rejected the idea that a strong likelihood of success could make up for showing only a possibility (rather than a likelihood) of irreparable harm. In other words, the Court ruled that the movant always must show a likelihood of irreparable harm.").

Over the course of the dozen years or so since the Supreme Court's decision in *Winter*, however, the D.C. Circuit has not found an occasion to expressly resolve the fate of the sliding-scale approach. *See Archdiocese of Washington*, 897 F.3d at 334 (stating that the case presented no occasion to decide whether the sliding-scale approach has continuing vitality after *Winter*); *League of Women Voters of United States v. Newby*, 838 F.3d 1, 7 (D.C. Cir. 2016) (same). Instead, it has left the question open and avoided it in at least one case by holding that the moving party failed to establish that injunctive relief was appropriate "even under the less demanding sliding-scale analysis." *Sherley*, 644 F.3d at 393; *see also Aamer v. Obama*, 742 F.3d 1023, 1043 (D.C. Cir. 2014) (stating that the fate of the sliding-scale approach "remains an open question"). Applying the sliding-scale approach means that "in cases where the other three factors strongly favor issuing an injunction, a plaintiff need only raise a 'serious legal question' on the merits" rather than demonstrating that success is "likely." *Aamer*, 742 at 1043 (quoting *Sherley*, 644 F.3d at 393, 398)). In any event, the Court need not attempt to reconcile the tension between the Supreme Court's decision in *Winter* and the D.C. Circuit's sliding-scale approach because Mallinckrodt cannot establish that the required factors favor a stay even if the sliding-scale approach is applied.

The Court will address each of the factors in turn, beginning, as it must, with the likelihood of success on the merits and irreparable harm, which the prior discussion foreshadows as being "the most critical." *Nken*, 556 U.S. at 434. If Mallinckrodt satisfies these two factors,

"the traditional stay inquiry calls for assessing the harm to the opposing party and weighing the public interest," although "[t]hese factors merge when the Government is the opposing party," as is the case here. *Id.* at 435.

A. Likelihood of Success on the Merits

Mallinckrodt must demonstrate that it is likely to succeed on the merits of its appeal to prevail on its motion for a stay. *See Citizens for Responsibility & Ethics in Washington v. Fed. Election Comm'n*, 904 F.3d 1014, 1019 (D.C. Cir. 2018) (noting that when an appeal "shows little prospect for success" that is "an arguably fatal flaw for a stay"); *Apotex, Inc. v. Food & Drug Admin.*, 449 F.3d 1249, 1253 (D.C. Cir. 2006) (dispensing with the need to consider the other stay factors when success on the merits was unlikely). Mallinckrodt contends that it will succeed on the merits of an appeal because the Court misinterpreted the provisions of the Medicaid Drug Rebate Program statute that apply to "single source drugs" and "[t]here simply can be no dispute at this point that under 42 U.S.C. § 1396r-8(c)(2)(A), if a drug product is a distinct 'single source drug,' it is entitled to its own base date AMP—*whether or not* it is an 'entirely new drug.'" Mallinckrodt's Br. 4, 9 (quotation). Mallinckrodt also argues that the Court "gave too short shrift to CMS's own regulations," *id.* at 9, and overlooked what Mallickrodt views to be inconsistent explanations CMS advanced for initially authorizing the company to set a new base date AMP for Acthar but then later negating that authorization, *id.* at 10. Mallinckrodt further challenges the Court's determinations that CMS's actions did not violate principles of fair notice and retroactivity. *Id.* at 12.

Like Mallinckrodt's request for reconsideration, its request for a stay reprises the same arguments the company presented to the Court during the litigation of the parties' motions for summary judgment, which were considered and resolved in the Court's March 13, 2020

memorandum opinion. Mallinckrodt offers nothing new in the way of legal arguments and the Court stands by the analyses set forth in that opinion, which explains why Mallinckrodt's arguments are unconvincing and forestalled by the Medicaid Drug Rebate Program statute's plain language. *See* Mem. Op. 30–49. Nevertheless, confronted by Mallinckrodt's persistent effort to convince the Court that the statute says something that it does not, the Court will walk through some of the essential points of the analyses again.

To reiterate, the question in this case is whether CMS properly determined that Mallinckrodt has been using the wrong base date AMP to calculate federally mandated rebates that Mallinckrodt must pay for the H.P. Acthar Gel® pharmaceutical drug under the statutory Medicaid Drug Rebate Program, which is part of the Medicaid Act, otherwise known as Title XIX of the Social Security Act, 79 Stat. 343 (codified as amended at 42 U.S.C. §§ 1396–1396v). Mallinckrodt agrees that the relevant section of the Medicaid Drug Rebate Program statute that establishes how it must calculate Achtar's rebates is 42 U.S.C. § 1396r-8(c), which is the section that applies to "single source drugs." *See* Mallinckrodt's Br. 4. The statute currently defines the phrase "single source drug" to mean in relevant part "a covered outpatient drug . . . which is produced or distributed under a new drug application [NDA] approved by the Food and Drug Administration." 42 U.S.C. § 1396r-8(k)(7)(iv).

Mallinckrodt's entire case is premised on convincing the Court that Acthar with the infantile spasm indication qualifies as a "distinct" single source drug from the version of Acthar that the FDA approved in 1952 under NDA number 008372. *See* Mallinckrodt's Br. 4 (asserting that "because Acthar constitutes a legally distinct 'single source drug,' it is entitled to a new base date AMP based on the plain language of the statute"). To get there, Mallinckrodt claims that Acthar has been "produced and distributed" under NDA number 022432, which was an efficacy supplement application that started out as Supplement Number S-039 to NDA number 008372 but was later

provisionally categorized as a "Type 6 NDA" by the FDA and assigned number 022432 solely as a bureaucratic mechanism to secure the application's review by a different FDA division from the one that first evaluated it.[5] *See supra* n. 3; A.R. 157, 344, 856–57, 869. Importantly, Mallinckrodt does not dispute that the Type 6 designation "was used for drug products *that had already been approved or marketed by the same applicant*, but were intended for a new indication or claim," *id.* ¶ 30 (emphasis added). Equally important is the fact that Mallinckrodt has never disputed that Acthar with the infantile spasm indication is not a new drug, *see* Mallinckrodt's Reply Br. 5 (arguing that CMS "could not possibly have assumed that it was approving an 'entirely new drug'" based on "references" to Acthar's history in the record), and that what the FDA approved in 2010 was the drug's use for a new indication and revised labeling, *see id.* (conceding that the 2010 approval involved "a decades-old drug, approved for a new orphan indication under a distinct NDA").

Additionally, Mallinckrodt has never disputed the fact that, when the FDA approved the efficacy supplement application that was provisionally assigned NDA number 022432, the agency told Mallinckrodt's predecessor, Questcor, to address all submissions "to the original NDA 008372 *for this drug product*"[6] and stop using NDA number 022432, A.R. 706 (stating "[i]n the future, do

[5] The FDA explained that "[i]n the case of Acthar Gel, the parent NDA (008372) and all of its supplements were reviewed by the Division of Metabolic and Endocrine Products" but "review of the infantile spasms indication was conducted by the Division of Neurology Products." A.R. 157. Mallinckrodt does not dispute that "[t]he agency took this action because it concluded the IS [infantile spasm] indication was fundamentally different from the other uses for which the product had been approved, and required review by a different component within FDA than had to date been responsible for the drug." Verified Compl. ¶ 30.

[6] The Court noted in the memorandum opinion that the FDA's October 15, 2010 letter approving NDA number 022432 made clear that the agency viewed Acthar with the infantile spasm indication to be the same drug product as the version of Acthar that was approved in 1952. Mem. Op. 18 (quoting A.R. 312 (stating that "all 'other submissions should be addressed to the *original NDA 008372 for this drug product*, not to this NDA'" (emphasis added))), 35.

not make submissions to this NDA [022432] except for the final printed labeling") (emphasis added). Thus, as of date the efficacy supplement application was approved in 2010, NDA number 022432 became obsolete and neither Questcor nor Mallinckrodt should have used it.

As the Court discussed in its memorandum opinion, absent Questcor's and Mallinckrodt's self-interested acts of "producing and distributing" Acthar using NDA number 022432 in defiance of the FDA's direction not to, the companies lack any plausible hook to claim that Acthar with the infantile spasm indication is a new or distinct "single source drug." Mallinckrodt's position is viable only if the Court either accepts or ignores the company's manipulation of the statute by producing and distributing Acthar using the defunct provisional NDA number that the FDA told the company not to use—a manipulation that Mallinckrodt seeks to further by applying a hyper-literal interpretation of the definition of "single source drug." Surely it is implicit in the statute that the covered outpatient drug at issue is legitimately and lawfully being "produced or distributed" under the claimed "new drug application" and "what is . . . implied in a statute . . . is as effectual as what is expressed." *Bd. of Sup'rs of Wood Cty. v. Lackawana Iron & Coal Co.*, 93 U.S. 619, 624 (1876). Otherwise, the purposes of the Medicaid Drug Rebate Program statute to provide medical assistance to the poor and facilitate that effort by minimizing drug costs could be easily avoided and even preposterous scenarios would permit manufacturers to lay claim to a new base date AMP.

For example, Mallinckrodt's theory would accommodate a less than honest manufacturer resetting a drug's base date AMP by suddenly producing and distributing an existing drug using an FDA-approved NDA number that applied to an entirely different drug. There might be other regulatory mechanisms that make that scenario improbable if not impossible, but one can see the point. By Mallinckrodt's reckoning, such a scenario would satisfy the statute because all that is required to set a new base date AMP, so Mallinckrodt argues, is a literal showing that a covered

outpatient drug is being "produced or distributed" under a "new drug application approved by the FDA"—and it does not matter whether that NDA involved the FDA approving something other than a "drug" (such as a label revision, as is the case here), or that the application was rendered obsolete upon approval so no drug could be "produced or distributed" under it (as is also the case here), or that the application was for a different drug entirely (hypothetical). Mallinckrodt has reaped a true windfall to the determent of both the nation's poor and its taxpayers by adhering to this legally untenable position.[7]

Moreover, as the Court explained in its memorandum opinion, even if Mallinckrodt's interpretation of the "single source drug" definition could carry the day, it still cannot prevail on the merits because a single source drug's base date AMP is set based on when the relevant "covered outpatient drug" was "approved by" the FDA and it is not, as Mallinckrodt insists, automatically set based on whether a covered outpatient drugs qualifies as a "single source drug."[8] Mem. Op. 32–42. Contrary to Mallinckrodt's position, this is what the Medicaid Drug Rebate Program statute actually says about the additional rebate for single source drugs and, in particular, when the base date AMP may be set:

[7] The Court finds it noteworthy that Mallinckrodt has never come forward with an example of an occasion when CMS authorized a new base date AMP for a drug based solely on the FDA approving an efficacy supplement application for that drug, whether in the form of a "new drug application" or otherwise.

[8] Mallinckrodt characterizes this as a "different test." Mallinckrodt's Br. 4. The only test the Court applied in this case, however, was a test that asked what the statute actually says. The issue the Court "homed in on," Mallinckrodt's Br. 5, was whether the statutory definition of "single source drug" can be satisfied when the FDA-approved NDA at issue does something other than "approve" a "drug," such as by approving a label revision, as is the case here, Mem. Op. 40 (stating that "[n]owhere in the Medicaid Drug Rebate Program statute does it provide for a single source drug's base date AMP to be reset based solely on the FDA approving a so-titled 'New Drug Application' that does something other than 'approve' a 'covered outpatient drug,' as occurred here").

> (A) In general
>
> The amount of the rebate specified in this subsection for a rebate period, with respect to each dosage form and strength of a single source drug or an innovator multiple source drug, shall be increased by an amount equal to the product of--
>
> (i) the total number of units of such dosage form and strength dispensed after December 31, 1990, for which payment was made under the State plan for the rebate period; and
>
> (ii) the amount (if any) by which--
>
> (I) the average manufacturer price for the dosage form and strength of the drug for the period, exceeds
>
> (II) the average manufacturer price for such dosage form and strength for the calendar quarter beginning July 1, 1990 (without regard to whether or not the drug has been sold or transferred to an entity, including a division or subsidiary of the manufacturer, after the first day of such quarter), increased by the percentage by which the consumer price index for all urban consumers (United States city average) for the month before the month in which the rebate period begins exceeds such index for September 1990.
>
> (B) Treatment of subsequently approved drugs
>
> In the case of a covered outpatient drug approved by the Food and Drug Administration after October 1, 1990, clause (ii)(II) of subparagraph (A) shall be applied by substituting "the first full calendar quarter after the day on which the drug was first marketed" for "the calendar quarter beginning July 1, 1990" and "the month prior to the first month of the first full calendar quarter after the day on which the drug was first marketed" for "September 1990".

42 U.S.C. § 1396r-8(c)(2).

The first highlighted subsection—§ 1396r-8(c)(2)(A)(ii)(II)—is the statutory base date AMP for drugs that the FDA approved on or before October 1, 1990.[9] *See, e.g.*, A.R. 1020 (National Drug Rebate Agreement). The second highlighted subsection—

[9] Mallinckrodt contends that this provision merely "sets the time period during which the base date AMP is *calculated*," Mallinckrodt's Br. 6 (emphasis in original), but the National Drug Rebate Agreement, to which Mallinckrodt is a party, says otherwise and states that this provision is *the* "base date AMP." *See* A.R. 1020 (defining the term "base date AMP" to mean 42 U.S.C.

§ 1396r-8(c)(2)(B)—amends the language of the base date AMP (i.e., it modifies § 1396r-8(c)(2)(A)(ii)(II)) to cover outpatient drugs that the FDA approved after October 1, 1990. In other words, for outpatient drugs that the FDA approved after October 1, 1990, § 1396r-8(c)(2)(A)(ii)(II), as amended by § 1396r-8(c)(2)(B), states that the base date AMP is:

> [T]he average manufacturer price for such dosage form and strength for *the first full calendar quarter after the day on which the drug was first marketed* (without regard to whether or not the drug has been sold or transferred to an entity, including a division or subsidiary of the manufacturer, after the first day of such quarter), increased by the percentage by which the consumer price index for all urban consumers (United States city average) for the month before the month in which the rebate period begins exceeds such index *the month prior to the first month of the first full calendar quarter after the day on which the drug was first marketed*.

42 U.S.C. §§ 1396r-8(c)(2)(A)(ii)(II), (B) (emphases added).

Importantly, the language in the second highlighted subsection—§ 1396r-8(c)(2)(B)—expressly states that a covered outpatient drug's base date AMP is set in relation to when the "covered outpatient drug" was "approved by" the FDA and "first marketed." Thus, the plain language of the statute cannot be harmonized with Mallinckrodt's theory that the base date AMP is tied to whether a drug satisfies the statutory definition of "single source drug" and, if so, then a new base date AMP is automatic. Mallinckrodt's Br. 4. That is simply not what the statute says.

Mallinckrodt's argument might be viable if § 1396r-8(c)(2)(B) stated that "[i]n the case of a *single source drug* approved by the Food and Drug Administration after October 1, 1990, clause (ii)(II) of subparagraph (A) shall be applied by substituting 'the first full calendar quarter after the day on which the drug was first marketed' for 'the calendar quarter beginning July 1, 1990' and 'the month prior to the first month of the first full calendar quarter after the day on which the drug was first marketed' for 'September 1990.'" But Congress omitted the phrase

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§ 1396r-8(c)(2)(A)(ii)(II)).

"single source drug" from § 1396r-8(c)(2)(B) and, instead, elected to use a different phrase—"covered outpatient drug." And it is well established that "[w]hen Congress uses explicit language in one part of a statute to cover a particular situation and then uses different language in another part of the same statute, a strong inference arises that the two provisions do not mean the same thing." *Persinger v. Islamic Republic of Iran*, 729 F.2d 835, 843 (D.C. Cir. 1984). Congress could have used the phrase "single source drug" in § 1396r-8(c)(2)(B) but it chose not to, and that has meaning. *Id.*

Consequently, even assuming for the sake of argument that Mallinckrodt was legitimately producing and distributing Acthar under defunct and provisional Type 6 NDA number 022432, the drug's base date AMP nevertheless would still be tethered to the date the FDA approved Acthar, which there is no dispute was 1952. *See, e.g.*, A.R. 51; Mallinckrodt's Br. 7 (conceding that "the second NDA covered only two changes: (i) approval of the infantile spasm indication and (ii) new labeling"); Mallinckrodt's Reply Br. 5 (conceding that Acthar was a "decades-old drug product"). That is what the Medicaid Drug Rebate Program statute's plain and unambiguous language demands.

Mallinckrodt cited no precedent, statutory provision, or any other authority to support its self-serving theory that a new base date AMP is automatic if the definition of single source drug is triggered and notwithstanding that the "new drug application" used to trigger it did something other than seek FDA approval of a covered outpatient drug, *see* Mallinckrodt's Br. 6 (arguing without cited authority that "[t]he drug product itself need not somehow change physically in order to count as a separate covered outpatient drug or qualify for a new base date AMP"). And, as the Court stated in its memorandum opinion, Mallinckrodt's theory flies in the face of the Medicaid Drug Rebate Program statute's legislative purpose, which is "to provide medical

assistance to poor people," Mem. Op. 7 (quoting *Indiana Family & Soc. Servs. Admin. v. Thompson*, 286 F.3d 476, 477 (7th Cir. 2002)), and to accomplish this in part by minimizing drug costs, *see* 42 U.S.C. § 1396r-8(b) (explaining that drug rebates serve to offset drug costs). Mallinckrodt's theory would not just circumvent the statute's goal of minimizing drug costs—it would defeat it.

The Medicaid Drug Rebate Program statute is technical and complex, but it is not ambiguous or silent. A single source drug gets a new base date AMP when the relevant "covered outpatient drug" is "approved by" the FDA and "first marketed" if that approval occurred after October 1, 1990. The statute expressly provides that the base date AMP attaches only once absent an FDA-approved new dosage form or strength. 42 U.S.C. § 1396r-8(c)(2). Again, it remains undisputed that no covered outpatient drug was approved by the FDA in 2010 under defunct and provisional NDA number 022432. To the contrary, in Mallinckrodt's own words, "the 2010 approval covered [1] a new IS indication; and [2] new labeling *for a decades-old drug product*." Mallinckrodt's Reply Br. 5 (emphasis added).

From the outset, CMS properly adhered to the statute and told Mallinckrodt that it could not change the base date AMP of a drug product during that drug product's lifecycle, which is entirely consistent and compliant with the statute's plain language.[10] A.R. 617 (stating that the

[10] Mallinckrodt claims that "the agency's reference to replacing base date AMPs 'midway through the life of a product'—has nothing at all to do with how to set the base date AMP" and, instead, "relates to its rejection of Questcor's proposal that it be allowed to retain the same National Drug Code (NDC) for Acthar after the new base date AMP was implemented." Mallinckrodt's Br. 8. This is but one example of how Mallinckrodt appears to be dazzled by its own litigation strategy much like the proverbial emperor who is wearing no clothes but is convinced he is wearing a new suit that is invisible to the commoners. CMS's letter allowing Questcor to set a new base date AMP for Acthar with the infantile spasm indication stated that the agency could not replace the "original" base date AMP for a drug product with a new base date AMP midway through the life of a product. A.R. 617. That statement means exactly what it says. It was made in the context of CMS explaining why Questcor could not keep the same

base date AMP applies to "each single source or innovator multiple source drug approved by the FDA before or after October 1, 1990" and that CMS lacked authority to "replace the original . . . base date AMP with a new base date AMP midway through the life of a product"). And, as the Court previously found, "[f]or the[] same reasons" that CMS's decision complied with the statute it "also complied with its agency regulations," which follow the language of the statute. Mem. Op. 42; *see also* 42 C.F.R. § 447.509.

The Court is not immune to the fact that, aside from the parties' discussions of the legal proceedings in *Ipsen Biopharms., Inc. v. Price*, No. 16-cv-2372 (DLF), the statutory question in this case does not appear to have been tested by other federal courts, although that might be because the statute is clear. At best, though, the potential novelty of the question inches the probability of Mallinckrodt's success on the merits closer to "possible," but nowhere near "likely," as required to establish that a stay is warranted pending appeal, *see Winter*, 555 U.S. at 21–22. The Court simply cannot conclude on this record that Mallinckrodt raises issues "so

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National Drug Code after setting a new base date AMP for Acthar, but its meaning is clear and has everything to do with the agency's view about when a new base date AMP could be set for a drug product. CMS was telling Questcor that, because the existing National Drug Code associated with Acthar was linked to Achtar's original NDA number 008372, in order to set a new base date AMP for the "recently approved Acthar Gel" (note that CMS did not say the "recently approved label revision" or "recently approved addition of an infantile spasm indication," suggesting, again, that CMS was under the mistaken impression that Acthar with the infantile spasm indication was approved as an entirely new drug product) Questcor would, as a corollary, have to obtain a new National Drug Code to go with what CMS understood to be the new NDA number—022432—because it could not change the base date AMP for NDA number 008372 during the lifecycle of that drug product. A.R. 617. At that point, Questcor was on obvious notice that CMS interpreted the Medicaid Drug Rebate Program statute to permit the calculation of a new base date AMP for Acthar with the infantile spasm indication only because CMS viewed Acthar with the infantile spasm indication to be a different "drug product" from the "original product," based on the fact that Questcor had reported that the drug was approved under a different NDA, in which case it would need a new National Drug Code associated with the new NDA because the "original" drug product's base date AMP could not be changed during its lifecycle. A.R. 617 (distinguishing Acthar with the infantile spasm indication as different "from the original product").

serious, substantial, difficult and doubtful, as to make them a fair ground for litigation and thus for more deliberative investigation." *Washington Metro. Area Transit Comm'n v. Holiday Tours, Inc.*, 559 F.2d 841, 844 (D.C. Cir. 1977). Finally, in light of the Court's statutory analysis and for the reasons set forth in the Court's March 13, 2020 memorandum opinion, Mallinckrodt is also not likely to prevail on its requests for relief pursuant to asserted fair notice and retroactivity principles.

B. Irreparable Harm

With respect to Mallinckrodt's requirement to establish that it will be irreparably harmed unless the Court issues a stay of its judgment, Mallinckrodt claims that it faces an "existential threat" posed by "significant financial, structural, and reputational harms to the company" if CMS declares it to be out of compliance with the Medicaid Drug Rebate Program requirements, which might occur if the defendants act to enforce the Court's judgment and Mallinckrodt fails to correct Acthar's base date AMP. Mallinckrodt's Br. 13. In particular, Mallinckrodt states that it will (1) be unable to report or revise Acthar's drug pricing data if CMS locks it out of the federal database that administers the drug rebate program, (2) risk being subjected to civil monetary penalties for its noncompliance, and (3) risk that its National Drug Rebate Agreement will be temporarily suspended, which means states "will no longer be required to cover Mallinckrodt's covered outpatient drugs, including Acthar." *Id.*

Moreover, even if Mallinckrodt alternatively elects to revise Acthar's base date AMP to comply with the statute, the company asserts that the revised based date AMP will trigger irreparable injury in the form of liability for "more than $600 million in additional Medicaid rebates that would come due to State Medicaid agencies almost immediately." *Id.* Mallinckrodt laments that this would cause a "cash-flow problem for the company" and, if paid, "would be recoverable only very slowly, over many years, from State Medicaid agencies, because of how

the recovery process works," which would entail offsetting the rebate overpayments against future Acthar rebate payments. *Id.* at 13–14.

The D.C. Circuit "has said time and again that the degree of proof required for 'irreparable harm' is 'high,' and that a failure to surmount it provides 'grounds for refusing to issue a preliminary injunction, even if the other three factors entering the calculus merit such relief.'" *Olu-Cole v. E.L. Haynes Pub. Charter Sch.*, 930 F.3d 519, 529 (D.C. Cir. 2019) (quoting *Chaplaincy of Full Gospel Churches v. England*, 454 F.3d 290, 297 (D.C. Cir. 2006)). As the D.C. Circuit has explained:

> Although the concept of irreparable harm does not readily lend itself to definition, the courts have developed several well known and indisputable principles to guide them in the determination of whether this requirement has been met.
>
> First, the injury must be both certain and great; it must be actual and not theoretical. Injunctive relief will not be granted against something merely feared as liable to occur at some indefinite time . . .; the party seeking injunctive relief must show that the injury complained of is of such imminence that there is a clear and present need for equitable relief to prevent irreparable harm.
>
> It is also well settled that economic loss does not, in and of itself, constitute irreparable harm. As this court has noted:
>
> > The key word in this consideration is irreparable. Mere injuries, however substantial, in terms of money, time and energy necessarily expended in the absence of a stay are not enough. The possibility that adequate compensatory or other corrective relief will be available at a later date, in the ordinary course of litigation weighs heavily against a claim of irreparable harm.
>
> *Virginia Petroleum Jobbers Ass'n v. FPC*, 259 F.2d at 925. Recoverable monetary loss may constitute irreparable harm only where the loss threatens the very existence of the movant's business.
>
> Implicit in each of these principles is the further requirement that the movant substantiate the claim that irreparable injury is "likely" to occur. Bare allegations of what is likely to occur are of no value since the court must decide whether the harm will in fact occur. The movant must provide proof that the harm has occurred in the past and is likely to occur again, or proof indicating that the harm is certain to occur in the near future. Further, the movant must show that the alleged harm will directly result from the action which the movant seeks to enjoin.

Wisconsin Gas Co. v. F.E.R.C., 758 F.2d 669, 674 (D.C. Cir. 1985) (per curiam) (citations and internal quotation marks omitted, alterations adopted). To be sure, the harms must be "beyond remediation" to qualify as "irreparable." *Chaplaincy of Full Gospel Churches v. England*, 454 F.3d 290, 297 (D.C. Cir. 2006). Accordingly, the Court will assess whether Mallinckrodt's asserted harms are actual, certain, imminent, beyond remediation, and, because most of the asserted harms are economic, threaten Mallinckrodt's very existence.

The only support Mallinckrodt proffers to prove its alleged harms are (a) the Declaration of Kathleen A. Schaefer in Support of Plaintiff's Motion for Preliminary Injunction, ECF No. 4-2, which was attached as Exhibit 2 to Mallinckrodt's original motion for a preliminary injunction, and (b) a transcript of Mallinckrodt's 2019 fourth quarter earnings call for investors, ECF No. 37-3, which was attached as Exhibit 3 to Mallinckrodt's motion for reconsideration. *See* Mallinckrodt's Br. 15 (citing the declaration and transcript), 17, 18. Kathleen Schaefer is Mallinckrodt's President. Schaefer Decl. ¶ 3. Her declaration lays out the harms that Mallinckrodt will suffer if CMS "declare[s] Mallinckrodt 'out of compliance' in the Drug Data Reporting for Medicaid (DDR) system based on the dispute over the base date average manufacturer price (AMP) for Acthar Gel® (repository corticotropin) injection (Acthar)." Schaefer Decl. ¶ 3. Those harms include: financial losses and reputational damage to Mallinckrodt if it is suspended from the Medicaid Drug Rebate Program, Schaefer Decl. ¶¶ 5, 6; loss of research and development investments, marketing efforts, and workforce, Schaefer Decl. ¶ 6; negative credit ratings, investment ratings, and declining stock prices, Schaefer Decl. ¶¶ 7, 8; reputational stigma and loss of good will among patients, healthcare professionals, and others, Schaefer Decl. ¶ 10; and civil monetary penalties to the tune of $10,000 per day, Schaefer Decl. ¶ 13. If Mallinckrodt revises Acthar's base date AMP to comply with the statute, Shaefer offers

that "[t]hat presents its own risks and liabilities," including "losses totaling in the hundreds of millions of dollars for Mallinckrodt." Schaefer Decl. ¶ 14.

With respect to the asserted economic harms, although Schaefer states that "CMS therefore has put Mallinckrodt between the proverbial rock and a hard place," Schaefer Decl. ¶ 14, nowhere does she state that the company's demise is or would be imminent, whether Mallinckrodt elects to correct Acthar's base date AMP or not. As a result, her declaration fails to corroborate the notion that Mallinckrodt will confront imminent demise absent a stay, and the economic harms otherwise do not demonstrate "irreparable" harm under this Circuit's precedent, *see, e.g., Wisconsin Gas Co.*, 758 F.2d at 674 (stating that "[r]ecoverable monetary loss may constitute irreparable harm only where the loss threatens the very existence of the movant's business").

Furthermore, Schaefer generally presents the reputational harms as possible, but not necessarily certain, stating that losses related to CMS enforcing the statute "could impact investor confidence" and prescribers and patients who switch to other treatments "may never return to Acthar." Schaefer Decl. ¶¶ 7, 10. Although she also states that a loss of investor confidence has resulted in a stock price decline and the loss of goodwill "can never be remedied," she fails to back that up with evidence or an explanation showing how or why the stock decline is irreversible or Mallinckrodt's reputation is forever tarnished. Schaefer Decl. ¶¶ 7–10. As a consequence, the Schaefer declaration does not adequately support granting a stay on the ground that Mallinckrodt will suffer irreparable harm without one. *Trudeau v. Fed. Trade Comm'n*, 384 F. Supp. 2d 281, 297 (D.D.C. 2005), *aff'd*, 456 F.3d 178 (D.C. Cir. 2006) (stating that "the showing of reputational harm must be concrete and corroborated, not merely speculative").

The transcript of the 2019 fourth quarter earnings call with investors that Mallinckrodt submitted fares no better and belies the notion that the company is facing imminent demise. That transcript reveals that Mallinckrodt's Vice President-Investor Relations and Investor Relations Officer, Daniel Speciale, reported that, "[w]hile we are not providing specific guidance due to the complexities of the settlement of financing in the Acthar CMS matter . . . [i]n general, total net sales for 2020 are expected to be in line with present consensus" and "we expect performance across the products to be weaker on a year-over-year basis in the first half of the year and rebounding in the back half of the year." Q4 2019 Earnings Call Tr. 2. Mallinckrodt's Chief Executive Officer, Mark Trudeau, was similarly equivocal but optimistic, referencing the "strong fourth quarter and full-year 2019 results," announcing a settlement of the opioid litigation that "is financially manageable and removes a significant uncertainty related to our business that will better enable us to move forward with our strategic plans and drive shareholder value," and stating that, while "there could be pressure on Acthar . . . [d]epending on the outcome of the CMS" litigation he nevertheless "do[es] expect the business to, overall, continue to generate significant cash flows."[11] Q4 2019 Earnings Call Tr. 2–3, 16.

As demonstrated, Mallinckrodt's two supplied sources of evidence offered to corroborate that it will be harmed without a stay plainly fail to establish that the asserted harm rises to the

[11] Mallinckrodt initially suggested that the potential $600 million rebate liability risked "disrupting other efforts by the company to right its financial ship," including the company's efforts to refinance its near-term debts. *See* Mallinckrodt's Reply Br. 10–11. The risk of that particular harm appears to have been resolved, however, at least in principle, by the company's reported negotiation of an exchange agreement to refinance nearly $500 million in debt. *See* Surreply in Opp'n to Pl.'s Emergency Mot. 2, ECF No. 44 (providing a link to a Securities and Exchange Commission (SEC) filing in which Mallinckrodt reported that the company entered into an exchange agreement to refinance nearly $500 million in debt).

level of "irreparable." *See, e.g.*, *Wisconsin Gas Co.*, 758 F.2d at 674. As a result, the Court cannot find that a stay is either warranted or appropriate under this factor.

C. Summary Conclusion

For all the foregoing reasons, the Court holds that Mallinckrodt has failed to establish that either success on the merits of an appeal or irreparable harm absent a stay are likely, in which case it cannot prevail regardless of whether the Court applies the legal standards set forth in *Winter*, 555 U.S. at 21–22, or the D.C. Circuit's sliding-scale approach, *see, e.g.*, *Sherley*, 644 F.3d at 392. The Court therefore need not consider the remaining factors, *CityFed Fin. Corp. v. Office of Thrift Supervision*, 58 F.3d 738, 747 (D.C. Cir. 1995), albeit suffice it to say that there is a strong public interest in ensuring that pharmaceutical companies are not circumventing the Medicaid Drug Rebate Program's purpose of minimizing Medicaid—and thereby taxpayers'—costs and diminishing the nation's ability to provide the medical services to the poor that Congress intended.

CONCLUSION

For the reasons set forth herein, the Court will deny Mallinckrodt ARD LLC's Emergency Motion for Reconsideration and Stay of Entry of Judgment Pending Reconsideration or, Alternatively, Injunction Pending Appeal, ECF No. 37. An appropriate order will be filed forthwith.

May 29, 2020

Thomas F. Hogan
SENIOR UNITED STATES DISTRICT JUDGE