IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

KALDEROS, INC. Plaintiff, v. UNITED STATES OF AMERICA, *et al.* Defendants.	No. 21-cv-02608 (DLF)

PLAINTIFF KALDEROS INC.'S MEMORANDUM OF POINTS AND AUTHORITIES IN OPPOSITION TO DEFENDANTS' MOTION TO STAY PROCEEDINGS

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Plaintiff Kalderos, Inc. respectfully submits this memorandum of points and authorities in opposition to Defendants' Motion to Stay Proceedings. Doc. No. 23 (Dec. 15, 2021) ("Motion to Stay" or "Motion"). For three reasons, the motion should be denied.

First, Defendants' motion is both unnecessary and premature. It is unnecessary because this Court already has granted Defendants an extension to respond to the Complaint until January 31st, well after the January 4th date by which they must decide whether to appeal the *Novartis/United Therapeutics ("Novartis/UT")* decision on which their Motion to Stay is based. It is premature because they seek a stay pending an appeal for an appeal they have not yet filed or decided to pursue. Defendants' request for a stay should be denied on these grounds alone.

Second, even if Defendants ultimately decide to appeal the Court's prior ruling in the *Novartis/UT* cases, a stay of Kalderos's lawsuit pending resolution of that appeal would be inappropriate. Defendants ignore the applicable legal standard, which requires them to show a stay is necessary to avoid a "clear case of hardship." *Landis v. N. Am. Co.*, 299 U.S. 248, 255 (1936). Defendants cannot meet that standard. The appeal will not address the conditions Kalderos is asserting as part of its model. Nor will it address the threshold objections Defendants apparently intend to assert to Kalderos's lawsuit, such as standing. This Court's prior ruling left open and expressly declined to address whether the distinct conditions at issue in the earlier lawsuits are lawful under the 340B statute. Likewise, the Court's prior decision could not have addressed the conditions associated with Kalderos's model, which, although they have features in common with those at issue in the claims-data portion of the *UT* case, differ from the conditions at issue in the earlier lawsuits.

Indeed, underscoring the need for Kalderos to proceed with litigation, Defendants simultaneously announce to drug manufacturers that they may not "permissibly condition access

to 340B priced drugs on covered entities' mandatory use of Kalderos's platform," Motion at 11, while insisting that Kalderos be prevented from litigating that issue until ***after both*** (i) Defendants decide whether to appeal and (ii) the D.C. Circuit issues a ruling on a decision that did not resolve that question as to the specific conditions imposed by Novartis and UT, let alone the specific conditions at issue in Kalderos's lawsuit.

Finally, a stay should be denied because the delay Defendants seek would severely prejudice Kalderos. Kalderos was compelled to file this action because of the significant harm Defendants' interpretation of the 340B statute is causing to Kalderos's business. That harm continues unabated and only this Court can remedy it. As noted, Defendants' motion doubles down on their position that the conditions associated with Kalderos's platform are unlawful, inflicting further harm on Kalderos and its ability to implement its 340B model. Absent a ruling by the Court striking down Defendants' unlawful policy forbidding ***any*** conditions to be imposed as part of the 340B program in the context of Kalderos's own model, Kalderos will continue to suffer these harms. Those harms cannot be remedied even after the D.C. Circuit considers an appeal of the *Novartis/UT* decision. That decision declined to address whether the conditions at issue in that case—which are distinct from Kalderos's—were permissible. Litigation following an appeal regardless of its outcome is inevitable because Kalderos must defend its model.

BACKGROUND

Plaintiff Kalderos, a technology company serving the healthcare industry, has developed an equitable, easy-to-use technology platform designed to ensure that 340B covered entities have confidence they are receiving the 340B prices to which they are entitled and that manufacturers have confidence they will not be subject to duplicate discounts and have some means to address diversion concerns. Complaint [Doc. 8] ("Compl.") ¶ 6. Kalderos seeks to be an honest broker that assists both covered entities and drug manufacturers in being able to have their reasonable

expectations met, with the goal of restoring both sides' confidence in the 340B program. In short, Kalderos seeks to administer 340B transactions in an efficient, legally compliant manner to the benefit of all stakeholders. *Id*.

In order for Kalderos's model to address duplicate discounts and diversion issues, as part of an effort to address all shareholders' concerns fairly and equitably, drug manufacturers require 340B covered entities to provide minimal claims information: the prescription or Rx number, prescriber identification number, national drug code, number of units, date of service, and 340B covered entity identification number. Compl. ¶ 62. This requirement is not restrictive as this kind of minimal information is routinely required by manufactures that offer price concessions to a broad range of non-340B customers, including managed care companies, hospitals, physician practices, retail pharmacies, group purchasing organizations, and States participating in the Medicaid program. *Id.* ¶ 63. It is also routinely required by non-manufacturer payors, like government programs and commercial payors, that reimburse 340B and non-340B pharmacies.

On December 30, 2020, the General Counsel of HHS issued an Advisory Opinion on contract pharmacy arrangements under the 340B Program. As part of this Advisory Opinion, HRSA stated its view that "[m]anufacturers cannot condition sale of a 340B drug at the 340B ceiling price because they have concerns or specific evidence of possible non-compliance by a covered entity." *See* 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 1210, 1223 (Jan. 5, 2017). After manufacturers filed suit challenging this position, a federal court in Delaware issued an order finding "the Opinion . . . legally flawed." *AstraZeneca Pharms. LP v. Becerra,* No. 1:21-cv-27, 2021 WL 2458063, at *8 (D. Del. June 16, 2021). Two days later, HHS withdraw the advisory opinion, although it continues to follow the very same policy.

On May 17, 2021, Defendant Diana Espinosa, in her official capacity as Acting Administrator of HRSA, sent letters to various drug manufacturers declaring that all conditions placed by manufacturers on their offers of 340B pricing are unlawful. Compl. ¶ 73. The letters state an absolute, unqualified position – without regard to the specifics of any manufacturer or the nature of any condition – that no condition of any kind may be required. Multiple manufacturers responded by filing suit challenging the agency's determination that manufacturers must provide 340B pricing on drugs dispensed through contract pharmacies. United Therapeutics ("UT") and Sanofi also challenged the agency's determination that manufacturers may not condition 340B prices on covered entities' production of claims data. *See United Therapeutics Corp. v. Espinosa*, No. 1:21-cv-01686-DLF (D.D.C. June 23, 2021); *Sanofi-Aventis U.S., LLC v. U.S. Dep't of Health & Hum. Servs.*, No. 3:21-cv-00634-FLW (D.N.J. Jan. 12, 2021). None of these companies had proposed to use Kalderos's model, so its conditions were not litigated as part of these cases.

For two and a half years, involving more than 20 contacts, Kalderos had communicated with HRSA to seek its review and approval of its model, because manufacturer clients repeatedly had declined to contract with Kalderos based on concerns about how HRSA would view its model. In the wake of the now-withdrawn Advisory Opinion and the May 17 letters, which foreclosed the use of any condition, Kalderos found its business line fundamentally challenged. Compl. ¶¶ 79-80. Kalderos's business line cannot proceed unless HRSA's policy, as applied to Kalderos, is set aside. These lost sales have continued up to the filing of this opposition and show no signs of abating. This case is critically important to Kalderos's business. To gain clarity and assurance, Kalderos engaged with HRSA following the issuance of the May 17 Letters. HRSA failed to provide any relief from its blanket policy against conditions.

With HRSA having stated and restated its "no conditions" policy now multiple times, Kalderos was forced to bring this action seeking declaratory and other relief necessary for its business to function. Kalderos filed suit on October 6, 2021, and due to some overlapping issues, filed a notice of related action with the *Novartis/UT* actions already pending before the Court. Defendants' original response deadline was December 17, 2021. In the *Novartis/UT* cases, on November 5, 2021, this Court (i) granted plaintiff's Motion for Summary Judgment in part and denied it in part and (ii) denied Defendants' Motion for Summary Judgment in its entirety. Kalderos did not participate in those proceedings and its model was not addressed by the Court's decision.

On November 24, 2021, Defendants sought Kalderos's consent to agree to a stay of the case, which Kalderos did not grant, explaining to Defendants the ongoing harm it would continue to suffer. On December 1, 2021, Defendants filed a request for an extension of time to respond to the complaint. Defendants stated that they planned to file a motion to stay the proceedings, while they decided whether to file an appeal in the *Novartis*/*UT* cases, and requested that the Court extend the time to respond to the complaint until three weeks after the Court resolved the upcoming motion for a stay or a stay was lifted. This Court granted and denied the motion in part, extending Defendants' deadline to respond to the complaint or request a stay until January 31, 2022. Defendants' deadline to file a notice of appeal in the *Novartis/UT* cases is January 4, 2022. Even though they had been given until January 31 to file a motion for a stay or to respond to the Complaint, and prior to deciding whether to appeal, Defendants filed the instant motion for a stay on December 15, 2021.

GOVERNING STANDARD

Defendants' description of the applicable law governing its stay request is critically incomplete. *See* Motion at 4-5. They acknowledge that *Hisler v. Gallaudet University*, 344 F.

Supp. 2d 29, 35 (D.D.C. 2004), announces the applicable standard as set forth in the Supreme Court's seminal decision in *Landis v. North American Co.*, 299 U.S. at 254, but they then omit the actual standard applied by the Court. As explained in *Hisler*, "[t]he Supreme Court has guided that 'the suppliant for a stay must make out a clear case of hardship or inequity in being required to go forward, if there is even a fair possibility that the stay for which [the movant] prays will work damage to some one else,'" and the movant therefore, "shoulders the burden in demonstrating a 'clear case of hardship.'" 344 F. Supp. 2d at 35 (quoting *Landis*, 299 U.S. at 255).[1] Indeed, "it is well established that a stay pending the resolution of unrelated legal proceedings is an extraordinary remedy." *Nat'l Indus. for the Blind*, 296 F. Supp. 3d at 137. Further, "'[o]nly in rare circumstances will a litigant in one cause be compelled to stand aside while a litigant in another settles the rule of law that will define the rights of both." *Belize Soc. Dev. v. Gov't of Belize*, 668 F.3d 724, 732 (D.C. Cir. 2012) (quoting *Landis*, 299 U.S. at 255). As shown below, Defendants' stay request should be denied because they have failed to show "a clear case of hardship" to support a stay opposed by Kalderos that would inflict significant continuing harm on Kalderos that cannot be remediated by the *Novartis/UT* appeal.

ARGUMENT

I. THE STAY SHOULD BE DENIED AS UNNECESSARY AND PREMATURE.

Defendants' request for a stay should be denied because (i) they do not need a stay to allow them time to decide whether to appeal, and (ii) a stay pending appeal is necessarily premature when Defendants have not yet even made a decision to appeal.

[1] *Accord Garcia v. Acosta*, 393 F. Supp. 3d 93, 110 (D.D.C. 2019) (recognizing authority to grant a stay but denying agency's stay request because "the interests of judicial economy" were "not enough" given the harm to plaintiff from a stay); *Am. Ctr. for Civil Justice v. Ambush*, 794 F. Supp. 2d 123, 130 (D.D.C. 2011) (denying stay because movant "failed to 'make out a clear case of hardship or inequity in being required to go forward'" (quoting *Landis*, 299 U.S. at 255)); *Nat'l Indus. for the Blind v. Dep't of Veterans Affairs*, 296 F. Supp. 3d 131, 143 (D.D.C. 2017) (denying stay where federal agency had "fallen far short of demonstrating that the current interest in judicial economy" outweighs "the harm that a stay of proceedings inflicts upon Plaintiffs").

First, on December 1, 2021, Defendants filed a Motion for an Extension of Time to Respond to the Complaint. *See* Doc. No. 20. Defendants argued that they needed additional time to allow them "to decide whether to file appeals" from the Court's November 5, 2021 Joint Memorandum and Order in *Novartis Pharmaceuticals Corp. v. Espinosa*, No. 1:21-cv-1479 (D.D.C.), and *United Therapeutics Corp. v. Espinosa*, No. 1:21-cv-1686 (D.D.C.). ECF Doc. 20 at 1-2. The same day, the Court granted Defendants' motion, in part, ruling that "Defendants shall answer or otherwise respond to plaintiff's Complaint, or move for a stay, on or before January 31, 2022." (Minute Order). Accordingly, Defendants have no obligation to answer or otherwise respond to Kalderos's Complaint until January 31, 2022.

As a consequence, there is no basis for Defendants' request for a stay to allow them to ***decide*** whether to appeal in the *Novartis/United Therapeutics* cases. *See* Motion at 1, 11. That relief already was requested by Defendants, was not opposed by Plaintiff, and was granted by the Court on December 1st. Any notice of appeal would be due on January 4, 2022. *See* Fed. R. App. P. 4(a)(1)(B); *see also* Motion at 11 (acknowledging that "[t]he deadline for any such decision [to appeal in the *Novartis/United Therapeutics cases*] is only a few weeks away."). There is no basis for further relief to allow Defendants to decide whether to file notices of appeal due on January 4, 2022.

Second, the request for a stay is otherwise premature because it is predicated on an appeal of the *Novartis/UT* decision. Indeed, Defendants' request for a stay "pending the D.C. Circuit's resolution of [*Novartis/UT*] cases" is dependent entirely on "if an appeal is taken." Motion at 1; *see also id.* at 5 ("if an appeal is taken"); *id.* at 11 ("And if the Government were to take an appeal, Defendants request a stay of proceedings only for the duration of that appeal."). Because

Defendants have not filed an appeal, their request for a stay pending appeal is premature and should be denied on that basis.

II. DEFENDANTS HAVE FAILED TO SHOW "A CLEAR CASE OF HARDSHIP" NECESSARY TO JUSTIFY A STAY IN THIS CASE.

Even if Defendants ultimately appeal the Court's ruling in the *Novartis/UT* cases, the request for stay should be denied because Defendants have failed to demonstrate "a clear case of hardship" as required by controlling precedent.

First, the Motion for Stay should be denied because Defendants ignore the governing legal standard. As the Supreme Court, D.C. Circuit, and courts within this District all have explained, the party seeking a stay of proceedings "shoulders the burden in demonstrating a 'clear case of hardship.'" *Hisler*, 344 F. Supp. 2d at 35 (quoting *Landis*, 299 U.S. at 255); *accord Dellinger v. Mitchell*, 442 F.2d 782, 786 (D.C. Cir. 1971). The "clear case of hardship" standard is nowhere mentioned or analyzed in Defendants' motion. Instead, Defendants suggest that entry of a stay sought by a movant is presumptively appropriate and that "[c]ourts within this District routinely stay proceedings where (as here) resolution of an appeal in another matter may guide the district court in deciding the issues before it." Motion at 5. That is wrong.

To the contrary, "it is well established that a stay pending the resolution of unrelated legal proceedings is an extraordinary remedy *Nat'l Indus. for the Blind*, 296 F. Supp. 3d at 137. Indeed, "[o]nly in rare circumstances will a litigant in one cause be compelled to stand aside while a litigant in another settles the rule of law that will define the rights of both." *Dellinger*, 442 F.2d at 786 (quoting *Landis*, 299 U.S. at 255). Defendants have made no effort to satisfy or even acknowledge that demanding standard.

Second, Defendants' reliance on what they contend would be "judicial economy" cannot and does not justify a stay of proceedings where, as here, the delay associated with a stay will

result in continuing harm to Kalderos. *See* Section III, *infra.* For example, in *Garcia v. Acosta*, 393 F. Supp. 3d at 110, the court denied a motion to stay predicated on "the interests of judicial economy," explaining that such an interest "is not enough," especially where the other proceedings upon which a stay was requested would not "moot the case." *Id.* Likewise, in *National Industries for the Blind*, the district court denied a request for a stay notwithstanding its acknowledgement that inefficiency should be avoided. 296 F. Supp. 3d at 143. The court there explained that a stay was unwarranted because a pending appeal was "unlikely to resolve all of the issues that [the Plaintiffs opposing the stay] raise in the instant consolidated matters." *Id.* The same is true in this case, as the Court's prior decision did not decide the lawfulness of the Novartis/UT conditions and, in any event, the Kalderos conditions are distinct from those in *Novartis/UT*.

A stay pending resolution of any appeal of the *Novartis/UT* cases would be inappropriate here because any appeal there cannot address the conditions reflected in Kalderos's model. To be sure, the Court's earlier decision addresses issues relevant to, and overlapping with, the relief sought by Kalderos. Nevertheless, the Court had no occasion to consider the specific conditions at issue in Kalderos's lawsuit when it addressed related claims brought by Novartis and UT. Indeed, in its decision, the Court expressly declined to "decide whether Section 340B permits or prohibits any of the specific conditions at issue [in the *Novartis/UT* cases]" because "the parties have not adequately argued their respective positions on Section 340B's structure." *Novartis Pharms. Corp. v. Espinosa,* No. 21-CV-1479 (DLF), 2021 WL 5161783, at *8 (D.D.C. Nov. 5, 2021).

Moreover, even if the Court had addressed the legality of the specific conditions at issue in Novartis and UT, that decision and any subsequent appeal would not resolve Kalderos's

circumstances.[2] The conditions at issue in Kalderos's Complaint differ from the conditions imposed by Novartis and UT. Kalderos's conditions "are intended to be similar to—or even easier to meet than—those that apply under traditional enrollment with a wholesaler by a covered entity, where the wholesaler submits 340B discount chargebacks to a manufacturer on behalf of a 340B covered entity." Compl. ¶ 61.[3] Indeed, the information requested under Kalderos's model "is routinely required by manufacturers that offer price concessions to a broad range of non-340B customers, including managed care companies, hospitals, physician practices, retail pharmacies, group purchasing organizations, and even States participating in the Medicaid program." *Id.* ¶ 63. In contrast, the conditions at issue in the *Novartis/UT* cases were materially different. Novartis' approach does not involve the use of claims data – at all. Although UT's does, it has features that are not claims-data based—and are not in any way part of the Kalderos model.[4] Further, the claims mechanism at issue in the UT case is a different approach employed by a different vendor. For instance, under that system, unlike Kalderos's, a commitment to provide data must be made, as we understand it, on a contract pharmacy by contract pharmacy basis. If a covered entity commits prospectively to provide claims data for a given contract pharmacy, that contract pharmacy will be permitted to have their 340B purchases authorized over a given period. If a covered entity decides

[2] Unlike most other litigants, Kalderos' case does not challenge the legality of "contract pharmacy transactions" under the 340B Program. Compl. ¶ 10 n.2. Kalderos' Complaint, reflecting its position as an honest broker between and among stakeholders, takes no position as to whether contract pharmacy transactions are contrary to the 340B statute. As explained in the Complaint, "Kalderos's solution will permit contract pharmacy transactions to be honored, subject only to reasonable conditions that permit an effective means to address duplicative discounts and diversion." *Id*. ¶ 53 n.8. Kalderos' model is designed to permit, not impede, appropriate contract pharmacy transactions.

[3] *See id.* ¶ 62 ("Among these terms and conditions is a requirement that covered entities, when submitting a request for 340B prices, provide certain minimal claims information. That claims information includes the Rx number, prescriber identification number, national drug code, number of units, date of service, and 340B covered entity identification number. This small set of data points is sufficient to enable Kalderos to address duplicate discounts and diversion issues.")

[4] For example, the UT option "honors only purchases directed to those contract pharmacies that were 'used by the related covered entity to make a valid 340B purchase of [its] drug[s] during the first three quarters of the 2020 calendar year.'" *Novartis*, 2021 WL 5161783 at *7. The Kalderos model permits an unlimited number of contract pharmacies.

not to commit prospectively to providing claims data for a given contract pharmacy, however, the manufacturer will preemptively deny all requests for 340B prices involving that contract pharmacy. Under the other system, then, the condition is applied at the contract pharmacy level, and affects all of a contract pharmacy's transactions for a given period. Kalderos's approach, instead, permits every contract pharmacy recognized by HRSA to continue to receive 340B prices, with the condition that, for an individual request for a 340B price, claims data be provided to indicate that the individual transaction does not appear to involve a duplicate discount or diversion.[5] Kalderos's model, thus, permits a 340B entity to provide information—or decide not to do so—on an individual claims basis. A failure to provide data on some transactions never prevents a 340B entity from receiving discounts on other transactions. Another difference is that the Kalderos model permits a direct payment of the discount to the 340B entity, speeding the time at which a 340B entity receives its funds—and giving it greater control over its contract pharmacies.

As a result, an indeterminate stay of Kalderos's lawsuit pending an appeal would not further judicial economy because any appeal from the *Novartis/UT* decision would not address the conditions in Kalderos's model. *See Nat'l Indus. for the Blind*, 296 F. Supp. 3d at 143 (denying stay where pending appeal "is unlikely to resolve all of the issues that Plaintiffs raise"). Indeed, Defendants insist, notwithstanding the Court's ruling in *Novartis/UT*, that "the balance of the case law does not currently support the conclusion that drug manufacturers could permissibly condition access to 340B-priced drugs on covered entities' mandatory use of Kalderos's platform." Motion at 11. That position only underscores that an appeal of *Novartis/UT* cases, even if it upholds this Court's decision, will still mean that Defendants' position will be that Kalderos's model is

[5] Among other differences, the Kalderos model thus permits a 340B covered entity to make decisions about whether or not to provide data with the maximum flexibility.

unlawful. The pressing need for timely resolution of Kalderos's Complaint is thus confirmed by Defendants' own arguments.

Defendants cannot exacerbate the concrete harm suffered by Kalderos by insisting both that Kalderos's model violates 340B and that Kalderos's challenge to that position must be delayed indefinitely by an appeal that has not been noticed and that, if noticed, would not resolve Kalderos's case. Defendants have not shown a "clear case of hardship" to support a stay.

III. KALDEROS WILL CONTINUE TO SUFFER HARM IF A STAY IS GRANTED.

Defendants' request for a stay also should be denied because Kalderos will suffer significant harm by a delay in resolution of its case. Defendants' arguments to the contrary are unavailing and underscore the unfairness of their stay request.

First, Defendants argue that Kalderos would not be harmed by a stay because Kalderos lacks standing to bring its claims. As an initial matter, it is fundamentally unfair for Defendants to request an extension of time to respond to the Complaint, by arguing its position on the merits of the Complaint in its motion for stay. *See* Motion at 2. This deprives Kalderos of the benefit of the full merits briefing process and attempts to force Kalderos to defend its position in the context of a procedural motion for which ***Defendants*** bear the burden of showing "a clear case of harm." If Defendants intend to challenge standing, they should abandon their motion for a stay and proceed with a properly supported motion under Rule 12.

Notably, in the present motion, Defendants do not explain why challenges to Kalderos's standing through a Rule 12 motion must wait until *after* an appeal—which would not address that issue—has concluded. Under Defendants' approach, Kalderos must wait until after an appeal has been filed, briefed, argued, and decided to address any challenges to Kalderos's complaint. This approach imposes undue delay on Kalderos. Rather, judicial efficiency and effective use of party

resources would be served by expeditiously adjudicating any issues such as standing, or disputes over the proper scope of the administrative record, in the ordinary course of litigation.

Second, the cases cited by Defendants do not support their request for a stay and, in fact, underscore what an extraordinary request Defendants are making. In *Alina Health Services v. Sebelius*, for example, the parties agreed that the pending appeal would be dispositive of the merits, and the appeal at issue had already been fully briefed and oral argument was scheduled to occur within 5 weeks from the date of the stay, with an opinion expected shortly after. 756 F. Supp. 2d 61, 71 (D.D.C. 2010). In *Cunningham v. Homeside Financial LLC*, the relevant appeal had already been argued and was simply waiting issuance of the opinion. No. MJG-17-2088, 2017 WL 5970719, at *2 (D. Md. Dec. 1, 2017). In *Ely v. United States Parole Commission*, oral arguments in the relevant appeal were scheduled for only a month after the stay was imposed. *See* No. 87-220, 1987 WL 11425, at *1 (D.D.C. May 20, 1987); *see also Fairview Hosp. v. Leavitt*, No. 05-1065, 2007 WL 152133, at *3 (D.D.C. May 22, 2007) (granting plaintiff's request for a stay pending a fully briefed summary judgment motion in a related case); *Tax Analysis & Advocates v. IRS*, 405 F. Supp. 1065, 1066 (D.D.C 1975) (parties had already fully briefed summary judgment which the court granted in part and held in part pending the outcome of a petition for certiorari); *New England Deaconess Hosp. v. Sebelius*, 942 F. Supp. 2d 56, 61 n.7, 64 (D.D.C. 2013) (lifting jointly requested stay which had been requested after the government had answered and filed the administrative record); *Kiakombua v. Wolf*, 498 F. Supp. 3d 1, 21 (D.D.C. 2020) (administratively staying case after parties had filed cross-motions for summary judgment pending an appeal that had already been fully briefed and argued), *appeal dismissed*, 2021 WL 3716392 (D.C. Cir. July 19, 2021); *Fonville v. Dist. of Columbia*, 766 F. Supp. 2d 171, 174 (D.D.C. 2011) (staying case

pending appeal that would be fully briefed one day after stay order).[6] These cases do not support the significant delay that Defendants are seeking to impose on Kalderos. Emboldened, as Defendants are, by their perception that some decisions, to date, have sufficiently supported their unlawful position that no condition can ever be imposed as part of the 340B program, it is clear that only a contrary decision involving a specific litigant will alter Defendants' view of that litigant and its legal position.

Third, Defendants are wrong in suggesting that Kalderos lacks standing. As Kalderos pled, "[i]n light of HRSA's new blanket policy forbidding manufacturer conditions, Kalderos has largely been unable to move forward with its model, with multiple manufacturers stating that they would contract with Kalderos for services, but cannot in light of Defendants' policy position." Compl. ¶ 10. Moreover as Kalderos explained in the complaint, "HRSA's new policy injures Kalderos by substantially reducing the demand for its services. Without the claims data Kalderos collects from covered entities, Kalderos's solution cannot function. Consequently, if manufacturers cannot require covered entities to produce claims data, few, if any, manufacturers will contract or persist in a contractual arrangement with Kalderos." Compl. ¶ 79. Kalderos has suffered clear and

[6] The other cases cited provide no support for a stay in this case. *See Gillick v. Willey*, No. 4:19-CV-03095 SEP, 2020 WL 5017291, at *1 (E.D. Mo. Aug. 25, 2020) (granting stay where respondents brief in the appeal at issue was due the day after the request and an opinion was expected a few months later); *Moskowitz v. Am. Sav. Bank, F.S.B.*, No. CV 17-00299 HG-KSC, 2017 WL 10661887, at *3 (D. Haw. Oct. 30, 2017) (granting "a short stay" where relevant appeal had already been briefed and argued and taken under submission); *Hussain v. Lewis*, 848 F. Supp. 2d 1, 2 (D.D.C. 2012) (staying motions to dismiss pending an arbitration); *IBT/HERE Emp. Representatives' Council v. Gate Gourmet Div. Ams.*, 402 F. Supp. 2d 289, 292 (D.D.C. 2005) (holding case in abeyance while the parties submitted to binding arbitration on the same issue remaining in the case); *Hughes v. Berryhill*, No. CV 16-352-ART, 2017 WL 3000035, at *1 (E.D. Ky. Feb. 21, 2017) (granting stay where plaintiff had already moved for class certification); *Walker v. Monsanto Co. Pension Plan*, 472 F. Supp. 2d 1053, 1055 (S.D. Ill. 2006) (staying several counts pending an appeal but allowing several other counts to move forward); *Lincoln Nat'l Life Ins. Co. v. Transamerica Fin. Life Ins. Co.*, No. 1:08-cv-135-JVB-RBC, 2010 WL 567993, at *1 (N.D. Ind. Feb. 12, 2010) (following a motion for summary judgment, granting a stay where relevant supreme court case had already been fully briefed and argued); *Coombs v. Diguglielmo*, No. CIV.A. 04-1841, 2004 WL 1631416, at *1 (E.D. Pa. July 21, 2004) (granting unopposed motion for a stay pending an appeal both parties agreed would be dispositive); *Felix v. United States*, No. C-91-0946-BAC, 1992 WL 361745, at *1 (N.D. Cal. Apr. 29, 1992) (seeking a limited stay of 90 days while government decided whether to file a writ of cert).

concrete economic harm to its business, which continues each day the case is pending. Because this is an APA matter, Kalderos cannot recover its economic losses from Defendants through damages. Kalderos's Complaint seeks to mitigate the harm through swift resolution of this action.[7]

Fourth, Defendants argue that because courts in other jurisdictions also have issued rulings that disagree with this Court's ruling, no decision by this Court would avoid the harm Kalderos is experiencing. That argument is wrong. The fact that courts have offered different assessments of relevant issues underscores the need for this Court to address a Kalderos-specific claim. Pointing to those other decisions, Defendants dismiss the significance of this Court's existing decision. Defendants' Motion confirms that they take the position that Kalderos's ***own specific conditions*** are unlawful under the same policy articulated in their May 17th letters. Citing the *Sanofi* and *Eli Lilly* opinions, Defendants argue that "the balance of the case law does not currently support the conclusion that drug manufacturers could permissibly condition access to 340B-priced drugs on covered entities' mandatory use of Kalderos's platform." Motion at 11. Thus, even in the face of this Court's clear opinion holding otherwise, Defendants maintain the position announced in their May 17th Letters and confirm that it applies to the Kalderos platform. Those admissions speak directly and persuasively as to why a stay is not appropriate here.

In a public judicial filing, Defendants have taken the position that the conditions necessary to facilitate Kalderos's model are unlawful, while at the same time seeking to prevent Kalderos from receiving expeditious judicial review of that position. Defendants' position necessarily

[7] Defendants' position that there is no standing because Kalderos "is not the subject of any enforcement action relating to HRSA's violation letters" is contrary to law. Motion at 10. Numerous courts have upheld standing in similar circumstances. *See, e.g.*, *Am. Fuel & Petrochemical Mfrs. v. EPA*, 3 F.4th 373, 379–80 (D.C. Cir. 2021), *petition for cert. filed* (U.S. Oct. 7, 2021) (No. 21-519); *Airlines for Am. v. TSA*, 780 F.3d 409, 410–11 (D.C. Cir. 2015); *Energy & Env't Legal Inst. v. Epel*, 793 F.3d 1169, 1175 n.1 (10th Cir. 2015) (Gorsuch, J.).

harms Kalderos by increasing manufacturers' reluctance to contract with Kalderos and thereby will cause further harm to Kalderos.

Finally, Defendants are simply wrong that no ruling from this Court could redress Kalderos's harm. What Kalderos seeks in this litigation is judicial consideration of the lawfulness of HRSA's policy as applied to Kalderos's circumstances, which are distinct from those in the *Novartis/UT* cases. A specific ruling from this Court in this matter would directly address the concerns of manufacturers who have declined to move forward with Kalderos's model.

CONCLUSION

For these reasons, Defendants' Motion to Stay should be denied.

December 22, 2021

Respectfully Submitted,

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