UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA

WHOLE WOMAN'S HEALTH ALLIANCE, *et al.*, Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, *et al.*, Defendants.	Case No. 3:23-cv-00019-RSB

DEFENDANTS' COMBINED SUPPLEMENTAL MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION AND REPLY IN SUPPORT OF DEFENDANTS' MOTION TO STAY PROCEEDINGS

BRIAN M. BOYNTON
Principal Deputy Assistant Attorney General

ARUN G. RAO
Deputy Assistant Attorney General

AMANDA N. LISKAMM
Director

HILARY K. PERKINS
Assistant Director

NOAH T. KATZEN
ISAAC C. BELFER
Trial Attorneys
Consumer Protection Branch
Civil Division
U.S. Department of Justice
P.O. Box 386
Washington, DC 20044-0386
(202) 305-2428 (Katzen)
(202) 305-7134 (Belfer)
(202) 514-8742 (fax)
Noah.T.Katzen@usdoj.gov
Isaac.C.Belfer@usdoj.gov

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INTRODUCTION

Plaintiffs' latest brief fails to show either that Plaintiffs are entitled to the extraordinary relief of a preliminary injunction[1] or that they will be prejudiced by a stay of proceedings. For the reasons set forth in Defendants' opening brief, at oral argument, and in this brief, the Court should deny Plaintiffs' Motion for Preliminary Injunction and grant Defendants' Motion to Stay Proceedings—or, alternatively, grant Defendants' Motion to Stay Proceedings and defer ruling on Plaintiffs' Motion for Preliminary Injunction until the resolution of appellate proceedings in *Alliance*.

First, Plaintiffs continue to fail to show any actual or imminent prospect of irreparable harm in the absence of an injunction. Plaintiffs do not dispute that the *Alliance* Order itself poses no imminent threat to them, as it has been stayed by the Supreme Court pending further appellate proceedings. At the June 8 hearing and again in their reply brief, Plaintiffs clarify that they believe that the "uncertainty" created by the possibility that the *Alliance* Order will eventually take effect causes them ongoing irreparable harm. *E.g.*, ECF No. 33 at 5–6; Transcript of June 8 Hearing (Tr.) at 10:18–20, 32:14–20, 74:10–13. But irreparable harm must be at least partly caused by the defendant, and the uncertainty Plaintiffs allegedly face is caused by the ongoing judicial proceedings in *Alliance*, not by FDA.

Plaintiffs' argument also collapses the well-established distinction between speculative harm and "actual or imminent" irreparable injury, rendering the mere

[1] Pursuant to the Court's direction, Defendants will limit this response to "new issues" raised by Plaintiffs at the June 8 hearing and in Plaintiffs' latest brief. ECF No. 29.

possibility of future injury an irreparable harm based upon how the plaintiff chooses to prepare for that possibility. And here the possibility of a cognizable injury is speculative. The only way the *Alliance* Order would take effect is if the Supreme Court grants certiorari and affirms it in whole or in part, or if the Fifth Circuit affirms it in whole or in part and certiorari either is not sought or is denied.

For the same reasons, Plaintiffs lack standing. Their alleged uncertainty-based injuries do not support Article III jurisdiction over their request for a preliminary injunction. Any uncertainty Plaintiffs face is caused by the ongoing judicial proceedings in *Alliance*, not by FDA. Moreover, costs that a plaintiff chooses to incur in anticipation of speculative future injury are neither an injury-in-fact nor fairly traceable to the defendant's challenged conduct. Plaintiffs also have not shown that their alleged uncertainty-based injuries are likely to be redressed by the requested preliminary injunction. Even if this Court issued the requested injunction, there would remain uncertainty regarding whether and how *Alliance* might ultimately be resolved by the Supreme Court.

In their reply, Plaintiffs take the novel position that they are not required to show standing to seek preliminary relief so long as they have standing to "bring this case" *(i.e.*, to seek some form of ultimate relief). ECF No. 33 at 4 (emphasis omitted). But Article III allows courts to resolve only justiciable cases or controversies, and this constitutional requirement applies to each form of relief a plaintiff seeks. Thus, courts

have required plaintiffs to show standing to seek a preliminary injunction even when the plaintiff's standing to seek the ultimate relief requested was not at issue.

Second, Plaintiffs fail to show that it would be appropriate for this Court to effectively grant them relief from an order by another district court (now stayed), rather than from the agency action they challenge. Plaintiffs misunderstand Defendants' argument that the relief Plaintiffs seek must be tailored to their specific claims, arguing that a preliminary injunction need not track the ultimate relief. Plaintiffs likewise misunderstand Defendants' argument that Plaintiffs may not collaterally attack the *Alliance* Order, arguing in essence that Plaintiffs are not collaterally estopped from bringing their claims. None of these arguments addresses Defendants' point: in a lawsuit against a federal agency under the Administrative Procedure Act (APA), plaintiffs can seek relief from only allegedly unlawful agency action, and not from another district court's order. Plaintiffs' requested preliminary injunction is not an appropriate form of relief because it is aimed at providing them relief from another district court's order (which may or may not ever take effect) and not from any allegedly unlawful FDA action.

Third, on the merits, Plaintiffs misstate Defendants' argument and overread Fourth Circuit precedent. Contrary to Plaintiffs' assertion, FDA *did* consider in connection with the January 2023 REMS modification whether a REMS with elements to assure safe use remains necessary, as Defendants pointed out in their opening brief. *See, e.g.*, ECF No. 27 at 25. And while *Mayor of Baltimore v. Azar*, 973 F.3d 258 (4th Cir. 2020), like many other cases, requires FDA to explain its reasoning, it does not require an

agency to take any special steps when it "disagrees with the consensus of the mainstream medical community." ECF No. 33 at 7. FDA gave a reasoned explanation for the January 2023 REMS modification, and that is all the APA and *Mayor of Baltimore* require.

Fourth, Plaintiffs are wrong to suggest that it would be inequitable for them not to receive the same relief from "uncertainty" that the preliminary injunction in *Washington v. FDA* provides to the plaintiffs in that case. The alleged uncertainty results from the judicial proceedings in *Alliance*, not action by FDA. And that uncertainty would not be remedied by the requested preliminary injunction because there would still be uncertainty about whether and how *Alliance* might ultimately be resolved by the Supreme Court. Notably, the *Washington* plaintiffs also face that uncertainty despite that court's preliminary injunction. Given that it is speculative how *Alliance* will ultimately be resolved, and how that may interact with the *Washington* order, among other things, Plaintiffs have not shown the requested injunction would even provide them the "certainty" they claim the *Washington* plaintiffs have.

Finally, Plaintiffs' arguments against a stay fail. Plaintiffs do not deny that the resolution of appellate proceedings in *Alliance* may provide this Court with guidance; they do not show that they will be prejudiced by deferring consideration of either their Motion for Preliminary Injunction or the merits; and they offer no compelling response

to Defendants' argument that Defendants will suffer hardship from having to continue litigating this case while the *Alliance* appeal is pending.

ARGUMENT

I. The Court Should Deny Plaintiffs' Motion For Preliminary Injunction

A. Plaintiffs Cannot Establish Irreparable Harm Or Standing Based On "Uncertainty" About *Alliance*

Plaintiffs do not deny that "the [Supreme Court's] stay in the *Alliance* case has averted (for now) the removal of mifepristone from the market or the reinstatement of [allegedly] burdensome restrictions." ECF No. 33 at 5. Instead, they contend "it is *the uncertainty* about how Plaintiffs and their patients are to respond to such events that is causing them irreparable harm." *Id.* at 6 (emphasis in original).

Although Plaintiffs concede that irreparable harm must be at least "partly perpetuated and caused by the defendant" to warrant a preliminary injunction, Tr. at 36:3, they do not explain how their alleged uncertainty-based injury was caused by FDA.[2] To the contrary, any uncertainty Plaintiffs face is caused, not by FDA, but by the

[2] At the hearing, Plaintiffs suggested that FDA is somehow partly to blame for their injuries because FDA had characterized mifepristone as "misbranded" in its Supreme Court stay application. Tr. at 32:14–20. But the government's stay application merely said that *if* the Fifth Circuit's modified *Alliance* Order had taken effect, that order *would have* rendered mifepristone misbranded with its existing labeling. Application to Stay the Order Entered by the United States District Court for the Northern District of Texas and for an Administrative Stay, at 4, *FDA v. Alliance for Hippocratic Medicine*, No. 22A902 (U.S. Apr. 14, 2023), https://perma.cc/KB9F-5VZM. Seven days after that application was filed, the Supreme Court issued its stay, obviating that hypothetical scenario. In any event, if Plaintiffs disagree with that statement, they did not explain their rationale at the hearing. Nor did they explain how FDA caused them injury by accurately describing the effect of another court's order. Notably, Plaintiffs do not repeat this argument in their latest brief.

ongoing judicial proceedings in *Alliance*. Indeed, Plaintiffs argue that "*the developments in the Alliance case* continue to cause uncertainty and chaos for Plaintiffs and the patients they serve." ECF No. 33 at 5 (emphasis added). Moreover, to the extent Plaintiffs and their patients may choose to incur costs to guard against the speculative possibility that the *Alliance* Order will ultimately be upheld in full or in part, such costs are self-inflicted and do not give rise to irreparable harm. *See Safari Club Int'l v. Jewell*, 47 F. Supp. 3d 29, 33 (D.D.C. 2014) (holding that irreparable harm "cannot arise from plaintiff's own actions"). Otherwise, *any* speculative harm could establish irreparable harm and standing simply by virtue of a plaintiff's own decision to expend resources in preparation for the possibility of that harm. Plaintiffs cite no authority for that novel theory, which would effectively permit preliminary injunctions based on "problematical and uncertain" rather than "present or immediate" harm, contrary to Fourth Circuit precedent. *See Direx Israel, Ltd. v. Breakthrough Med. Corp.*, 952 F.2d 802, 816 (4th Cir. 1991).

For similar reasons, Plaintiffs have not met their burden to show standing and thus have not established an Article III controversy over their request for a preliminary injunction. *See California v. Texas*, 141 S. Ct. 2104, 2113 (2021). They have not shown traceability because the "uncertainty" they face is caused by the judicial proceedings in *Alliance*, not by FDA. *See id.* Moreover, any costs Plaintiffs and their patients may choose to incur based on their speculative fears about how *Alliance* will ultimately be resolved are self-inflicted and thus do not show either an injury-in-fact or traceability. *See Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 417 (2013) (explaining that costs incurred

based on speculative fears are "insufficient to create standing"); *Buchanan v. Consol. Stores Corp.*, 125 F. Supp. 2d 730, 737 (D. Md. 2001) (self-inflicted injury is not an injury-in-fact under Article III).

Plaintiffs also have not shown that the requested preliminary injunction would likely redress their alleged uncertainty-based injuries. *See California*, 141 S. Ct. at 2113. Even if this Court were to issue the requested injunction, there would still be uncertainty about whether and how *Alliance* might ultimately be resolved by the Supreme Court. Should the Supreme Court rule in *Alliance* in a manner that conflicts with this Court's (or *Washington*'s) injunction, the Supreme Court's ruling would control. Given that it is uncertain and speculative how *Alliance* will ultimately be resolved, Plaintiffs have not met their burden to show that the requested preliminary injunction would likely redress their alleged injuries.

Despite Plaintiffs' assertions, ECF No. 33 at 4, there is no preliminary-injunction exception to the "irreducible constitutional minimum" of standing, *Lujan v. Def. of Wildlife*, 504 U.S. 555, 560 (1992), which requires a plaintiff to show injury, causation, and redressability "for each form of relief," *Davis v. FEC*, 554 U.S. 724, 734 (2008); *Friends of the Earth, Inc. v. Laidlaw Envt'l Servs.*, 528 U.S. 167, 185 (2000). Quoting *Town of Chester, N.Y. v. Laroe Estates, Inc.*, 481 U.S. 433 (2017), out of context, Plaintiffs suggest that they need only have standing to seek ultimate relief. ECF No. 33 at 4. But in fact, courts have held that plaintiffs must show standing to pursue a preliminary injunction, even when the plaintiffs' standing to pursue some form of ultimate relief was not at issue. *See, e.g.*, *Waskul v. Washtenaw Cnty. Community Mental Health*, 900 F.3d 250, 256–57

(6th Cir. 2018) (limiting review to whether plaintiff had standing to seek a "narrow" preliminary injunction and not considering other forms of relief); *Suzhou Angela Online Game Tech. Co. v. Snail Games USA, Inc.*, No. 22-55137, 2022 WL 5240656, at *1 (9th Cir. Oct. 6, 2022) (unpublished) (considering narrow question of whether plaintiff had "standing to seek a preliminary injunction"); *see also City of Los Angeles v. Lyons*, 461 U.S. 95, 105 (1983) ("Lyons has failed to demonstrate a case or controversy with the City that would justify the equitable relief sought," including a preliminary injunction, because he lacked "standing to seek the injunction").

Here, regardless of whether Plaintiffs have standing to seek the ultimate relief requested in the Complaint (*i.e.*, prohibiting FDA from enforcing or applying the mifepristone REMS, ECF No. 1, ¶ 159), Plaintiffs must show standing to seek the requested preliminary injunction (*i.e.*, prohibiting FDA "from altering the status quo and their rights, as they relate to the January 2023 [REMS modification]" in "Virginia, Montana, and Kansas, where Plaintiffs operate, pending a decision on the merits," ECF No. 8 at 3). Plaintiffs have failed to meet that burden.

B. The Relief Plaintiffs Seek Is Inappropriate

Even if Plaintiffs had shown irreparable harm caused by FDA and redressable by this Court, the relief they seek is an inappropriate means of redressing that harm, both because it is not tailored to Plaintiffs' claims and because it effectively seeks relief from another court's (stayed) order. *See generally Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S.

7, 32 (2008) (explaining that "[a]n injunction is a matter of equitable discretion"). Plaintiffs' responses are unpersuasive.

First, Plaintiffs misunderstand Defendants' argument that their requested relief is not tailored to their claims. Defendants did not argue that "Plaintiffs' irreparable harm [must] track the relief they are seeking on the merits of their ultimate claims." ECF No. 33 at 2. Rather, Defendants argued that any relief—including preliminary injunctive relief—must provide *some kind* of redress from an alleged legal wrong, which in an APA case must be an allegedly unlawful agency action. ECF No. 27 at 19; *accord Hill Dermaceuticals, Inc. v. FDA*, 709 F.3d 44, 46 n.1 (D.C. Cir. 2013). Here, Plaintiffs seek no preliminary relief from the only agency action they allege is unlawful: the January 2023 REMS modification. Indeed, they have expressly disclaimed seeking such an "extreme remedy." Tr. at 17:11–12. Rather, and paradoxically, Plaintiffs seek to preliminarily freeze in place the very agency action they contend is unlawful. Plaintiffs point to no case other than *Washington* where such relief was entered, or even sought by a party.

Second, Plaintiffs argue that they may ask this Court to effectively grant them relief from the *Alliance* Order because (1) the *Alliance* Order is not a final judgment and (2) Plaintiffs are not a party to *Alliance* or in privity with a party to that case. ECF No. 33 at 13. Neither argument supports the relief they seek. *See United States v. Terry*, 17 F.3d 575, 579 (2d Cir. 1994) (holding that defendant could not collaterally attack a preliminary injunction); *Cigar Ass'n of Am. v. FDA*, 411 F. Supp. 3d 1, 4 (D.D.C. 2019) (holding that one district court cannot provide relief from another district court's order where the party seeking relief was not a party to the case before the other court).

Defendants' point is not that Plaintiffs are collaterally estopped from litigating their claims, but simply that it is not proper for one district court to grant relief meant to impede the effect of another district court's ruling. *See Cigar Ass'n*, 411 F. Supp. 3d at 4 (refusing to create an "exception" or "carve-out" from another district court order). Plaintiffs cite no authority to the contrary.

C. Plaintiffs' New Merits Arguments Fail

On the merits, Plaintiffs' primary arguments in their reply are that (1) "[t]he government does not deny that FDA did not evaluate whether imposing a REMS generally continues to be appropriate in 2023," ECF No. 33 at 10, and (2) *Mayor of Baltimore* requires FDA to yield to an alleged consensus in the medical community that the REMS is unnecessary, ECF No. 33 at 7–9. Both arguments fail.

First, contrary to Plaintiffs' assertion, FDA *did* evaluate whether a REMS continues to be necessary. As Defendants explained in their opening brief, FDA determined that "[m]ifepristone will remain safe and effective for medical abortion if the in-person dispensing requirement is removed, provided all the other requirements of the REMS are met, and pharmacy certification is added …." ECF No. 27 at 25 (quoting Katzen Decl. Ex. C at 39). Defendants also cited the record, detailing FDA's findings on that very point. *See id.* (citing Katzen Decl. Ex. C at 14, 18, 36, 37, 39–40, 41; Katzen Decl. Ex. G.); *see also id*. at 7 ("FDA announced its conclusion that 'the

Mifepristone REMS Program continues to be necessary to ensure the benefits [of mifepristone] outweigh the risk[s]'" (quoting Katzen Decl. Ex. D at 6)).[3]

Second, Plaintiffs overread *Mayor of Baltimore*. There, the Fourth Circuit considered a Department of Health and Human Services (HHS) final rule that "prohibit[ed] physicians and other providers in Title X programs from referring patients for an abortion, even if that is the patient's wish," and instead "requir[ed] them to refer the patient for prenatal care." 973 F.3d at 266. The court found that, among other things, HHS arbitrarily and capriciously failed to explain its disagreement with "literally every major medical organization in the country" on "ethical concerns" with the rule. *Id. Mayor of Baltimore* does not require an agency to take any special steps when it "disagrees with the consensus of the mainstream medical community," ECF No. 33 at 7, especially in the context of drug safety, which is a matter within the agency's core expertise, *see Schering Corp. v. FDA*, 51 F.3d 390, 399 (3d Cir. 1995). Moreover, unlike HHS in *Mayor of Baltimore*, FDA's decision here did not merely state what the agency "'believe[d]' … without further support." *See* 973 F.3d at 276. Rather, FDA considered the extensive evidence before it, applied its expertise, and explained the reasoning for

[3] To be sure, FDA was not writing on a blank slate when it made this decision. It instead asked whether evidence that had arisen since the 2016 REMS modification demonstrated that the REMS was no longer necessary. *See* Tr. at 65:15–66:7. Plaintiffs do not show that undertaking this inquiry was arbitrary and capricious or otherwise unlawful.

its decision in detailed memoranda. *See* Katzen Decl. Ex. C; *see also id*. Ex. G. That is all *Mayor of Baltimore* and the APA require.

D. The Equities Do Not Require Extending The *Washington* Relief

Plaintiffs argue that it is inequitable for them not to obtain the same relief from the "uncertainty" created by the *Alliance* Order that the *Washington* plaintiffs have. ECF No. 33 at 11. But once more, the only source of the uncertainty that Plaintiffs point to is what another court in *Alliance* might do—not any action FDA might take of its own accord. Moreover, even if this Court were to issue the requested injunction, there would still be uncertainty about whether and how *Alliance* might ultimately be resolved by the Supreme Court. Of course, a preliminary injunction from this Court could not block any potentially conflicting ruling by the Supreme Court. Notably, this uncertainty in light of a possible Supreme Court decision in *Alliance* is also present in the *Washington* plaintiff states despite that court's preliminary injunction. Given that it is speculative how *Alliance* will ultimately be resolved, and how that may interact with the *Washington* order, among other things, Plaintiffs have not met their burden of showing the requested injunction would even provide them the "certainty" they claim the *Washington* plaintiffs have, and therefore of showing that such an injunction would be equitable.

II. The Court Should Grant Defendants' Motion To Stay Proceedings

As Defendants argued in their opening brief, this Court should stay proceedings pending resolution of the *Alliance* appellate proceedings. In response, Plaintiffs make three arguments. ECF No. 33 at 15–17. None is persuasive.

First, although Plaintiffs acknowledge that "there are similar questions of fact" in this case and *Alliance*, ECF No. 33 at 15; *see also* Tr. at 73:15–16, 83:5–8, they argue that it would not be efficient to stay this case pending resolution of the *Alliance* appellate proceedings because (1) "it is not assured that the Supreme Court will say anything about whether the 2023 REMS modification was unlawful," and (2) the *Alliance* appellate proceedings concern preliminary relief. ECF No. 33 at 15. But the relevant question is not whether it is "assured" that *Alliance* will provide guidance on the questions before this Court. Rather, the relevant question is whether action by the Supreme Court "*may* change the legal landscape." *Benisek v. Lamone*, 266 F. Supp. 3d 799, 808 (D. Md. 2017), *aff'd*, 138 S. Ct. 1942 (2018) (emphasis added); *see also Wikimedia Found. v. NSA*, 14 F.4th 276, 306 (4th Cir. 2021) (Motz, J., concurring in part and dissenting in part) (noting that it is "proper" to "stay[] proceedings while awaiting guidance from the Supreme Court in a case that could decide relevant issues" (quoting *Hickey v. Baxter*, 833 F.2d 1005 (4th Cir. 1987) (per curiam) (unpublished) (internal quotation marks omitted))). Plaintiffs do not deny that *Alliance* "may change the legal landscape." *Benisek*, 266 F. Supp. 3d at 808. Nor do they suggest that this Court would decline to consider such changes merely because *Alliance* came to the Supreme Court in a preliminary injunction posture. To the contrary, they conceded at the June 8 hearing that after resolution of *Alliance* appellate proceedings, "we would have guidance from the Supreme Court about the merits of this case, perhaps." Tr. at 73:15–16.

Second, Plaintiffs' arguments that they would be prejudiced by a stay are unavailing. Regarding Plaintiffs' preliminary injunction motion, although Defendants

maintain that the Court should deny that motion now and stay further proceedings, Defendants have proposed as an alternative that the Court defer consideration of that motion until after the requested stay terminates. Plaintiffs would not be prejudiced by deferring consideration of their motion until after resolution of the *Alliance* appellate proceedings because they have not shown how the stayed *Alliance* order presently injures them, as discussed above. Plaintiffs also would not be prejudiced by a stay of adjudicating their claims on the merits, as evidenced by their delay in bringing this case. Moreover, Plaintiffs conceded at oral argument that they "would perhaps not be opposed to staying the proceedings" if they obtain their requested preliminary injunction. Tr. at 82:10–11. Because their requested preliminary injunction would *maintain* the January 2023 REMS modification, rather than providing any relief from it, Plaintiffs' concession supports the conclusion that Plaintiffs would suffer no prejudice from deferring consideration of the merits of their challenge to the January 2023 REMS modification.

Third, even assuming Plaintiffs would suffer some prejudice from a stay, their contention that Defendants would not suffer greater hardship or inequity from being forced to litigate both here and in *Alliance* is incorrect. ECF No. 33 at 16. Indeed, while Plaintiffs repeat their arguments that it would not be inequitable to Defendants for the Court to grant the requested preliminary injunction, Plaintiffs have no response to

Defendants' argument that Defendants would suffer hardship from having to litigate the merits of this case while the *Alliance* appellate proceedings are pending.[4]

CONCLUSION

For the foregoing reasons, and for the reasons set forth in Defendants' opening brief and at the June 8 hearing, the Court should deny Plaintiffs' Motion for Preliminary Injunction and grant Defendants' Motion to Stay Proceedings. In the alternative, the Court should grant Defendants' Motion to Stay Proceedings and defer consideration of Plaintiffs' Motion for Preliminary Injunction until after the Supreme Court's stay in *Alliance* terminates.

June 30, 2023

Respectfully submitted,

/s/ Isaac C. Belfer
NOAH T. KATZEN
ISAAC C. BELFER
Trial Attorneys
Consumer Protection Branch
Civil Division
U.S. Department of Justice
P.O. Box 386
Washington, DC 20044-0386
(202) 305-2428 (Katzen)
(202) 305-7134 (Belfer)
(202) 514-8742 (fax)
Noah.T.Katzen@usdoj.gov

[4] At the June 8 hearing, the Court inquired whether there is "any reason that [it] shouldn't require production of the administrative record but then stay everything with respect to briefing." Tr. at 70:20–22. While Defendants believe a full stay would be appropriate, they are also amenable to the Court ordering the administrative record to be produced by September 1, 2023 (as Defendants have agreed in *Washington*), while staying summary judgment briefing.

Isaac.C.Belfer@usdoj.gov

Certificate of Service

I certify that the foregoing was served on all counsel of record via ECF on June 30, 2023.

/s/ Isaac C. Belfer
Isaac C. Belfer