

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

DAYTON AREA CHAMBER OF
COMMERCE *et al.*,

Plaintiffs,

v.

XAVIER BECERRA *et al.*,

Defendants.

Civil Action No. 3:23-cv-00156-MJN-PBS

Judge Michael J. Newman

Magistrate Judge Peter B. Silvain, Jr.

RULE 26(f) REPORT OF THE PARTIES

1. Pursuant to Fed. R. Civ. P. 26(f), counsel for the parties conferred via telephone and email on October 5, 18, 19, and 20. Those conversations included:

- Jeffrey S. Bucholtz, counsel for Plaintiffs
- Jennifer B. Dickey, counsel for Plaintiff Chamber of Commerce of the United States
- Stephen M. Pezzi, counsel for Defendants

2. The parties:

___ have provided the pre-discovery disclosures required by Fed. R. Civ. P. 26(a)(1), including a medical package (if applicable).

___ will exchange such disclosures by ____.

___ are exempt from disclosure under Fed. R. Civ. P. 26(a)(1)(E).

X do not intend to provide initial disclosures at this time, for reasons explained below in response to item 6.

3. The parties:

___ unanimously consent to the jurisdiction of the United States Magistrate Judge pursuant to 28 U.S.C. § 636(c).

X do not unanimously consent to the jurisdiction of the United States Magistrate Judge pursuant to 28 U.S.C. § 636(c).

— unanimously give contingent consent to the jurisdiction of the United States Magistrate Judge pursuant to 28 U.S.C. § 636(c), for trial purposes only, in the event that the assigned District Judge is unavailable on the date set for trial (e.g., because of other trial settings, civil or criminal).

4. Recommended cut-off date for filing of motions directed to the pleadings: See Plaintiffs’ and Defendants’ differing proposals below.

5. Recommended cut-off date for filing any motion to amend the pleadings and/or to add additional parties: 14 days after the filing of any motion to dismiss.

6. Recommended discovery plan:

The parties agree that no discovery is necessary at this time. Defendants intend to challenge both venue and subject-matter jurisdiction, but the parties do not expect that addressing those threshold arguments will require resolution of any disputed facts by the Court. If the Court reaches the merits, Plaintiffs bring a facial constitutional challenge to a federal statute, which can likewise be resolved without the need for resolution of any disputed facts.

7. Recommended dispositive motion date:

The parties agree that this case can and should be resolved via dispositive motion(s), but disagree regarding the appropriate schedule and sequencing of those motions. Despite a good-faith effort, the parties were unable to resolve that disagreement. The parties set forth their separate proposals below:

Plaintiffs’ Proposal

Plaintiffs respectfully submit that, in the interest of efficiency and avoiding unnecessary delay, the parties should proceed directly to cross-motions for summary judgment. Implementation of the IRA is already well underway and several key statutory deadlines are impending within less than a year, including the February 1, 2024 deadline for CMS to convey its “offer”; the March 2 deadline for manufacturers to accept that “offer” or submit a “counteroffer”; the August 1 deadline for CMS to set the “maximum fair price”; and the September 1 deadline for CMS to publish the “maximum fair price.” The “negotiation” process will require extensive time and effort by Plaintiffs’ members throughout the coming months to evaluate CMS’s “offer” and to prepare a “counteroffer.” And

Plaintiffs' members will have no choice but to "agree" to the "maximum fair price" as of August 1 if they are unable to obtain judicial relief by that time. It is therefore critical for this case to be ready for decision on the merits in advance of that deadline (and far enough in advance of that deadline to allow time for either side to appeal and, if necessary, to seek emergency relief); otherwise, Defendants will have succeeded in running out the clock. In addition, Plaintiffs' members need to prepare for CMS's selection of an additional 15 drugs by February 1, 2025, including undertaking another round of complex data collection for potential submission to CMS.

Given those time sensitivities, in another case challenging the constitutionality of the IRA, the parties agreed to a briefing schedule that would allow the District of Delaware to rule on the merits by March 1, 2024. *See AstraZeneca Pharms., LP v. Becerra*, No. 1:23-cv-931, Dkt. 15 (D. Del. Sept. 19, 2023). The court adopted that "Target Decision Date." *Id.* ¶ 6. Plaintiffs respectfully request that this Court adopt the same target decision date. To afford this Court adequate time to issue a decision on the merits by March 1 or shortly thereafter, summary judgment briefing needs to conclude far enough in advance of that date to afford the Court time to consider the briefs, hold oral argument if desired, and prepare a decision. Plaintiffs' schedule proposed below would achieve this goal.

"It is well-established law that 'a district court has broad discretion to manage its docket.'" *Ramsey v. Receivables Performance Mgmt., LLC*, No. 1:16-CV-1059, 2019 WL 1054550, at *2 (S.D. Ohio Mar. 6, 2019) (quoting *Am. Civ. Lib. Union of Ky. v. McCreary Cnty., Ky.*, 607 F.3d 439, 451 (6th Cir. 2010)). And "[w]here," as here, "the question before the court is purely a legal one, the summary judgment procedure is well suited for resolution of the case." *Bajraszewski v. Allstate Ins. Co.*, 825 F. Supp. 2d 873, 877 (E.D. Mich. 2011) (citing *Cincom Sys., Inc. v. Novelis Corp.*, 581 F.3d 431, 435 (6th Cir. 2009)). If Defendants wish to make non-merits arguments, like those addressing jurisdiction or venue, nothing would prevent them from incorporating those arguments into a cross-motion for summary judgment. *See, e.g., Blane v. Am. Inventors Corp.*, 934 F. Supp. 903, 905 (M.D. Tenn. 1996) (considering venue argument on cross-motions for summary judgment). The only practical difference would be that, if this Court rejects those procedural arguments, it could proceed immediately to the merits instead of having to issue an initial non-merits ruling, then wait for the parties to complete a

third round of briefing, and only then begin to consider the merits, all the while leaving Plaintiffs no choice but to comply with a “negotiation” process they challenge as unconstitutional. Plaintiffs therefore propose that the Court enter the following briefing schedule:

- Plaintiffs’ motion for summary judgment: November 3, 2023
- Defendants’ cross-motion for summary judgment / opposition to Plaintiffs’ motion for summary judgment: December 8, 2023
- Plaintiffs’ reply / opposition to government’s cross-motion for summary judgment: January 10, 2024
- Defendants’ reply: January 31, 2024

That schedule would ensure that this Court has the opportunity to consider the merits in timely fashion while still allowing Defendants to make any procedural arguments they would otherwise have made in a motion to dismiss (or raise any defenses they would otherwise have raised in an answer).

None of Defendants’ objections to that common-sense approach holds up to scrutiny. First, Defendants say they plan to raise “non-merits arguments on both jurisdiction and venue.” But again, Defendants can raise those arguments just as easily in a cross-motion for summary judgment. That Defendants hope to avoid ever addressing Plaintiffs’ arguments on the merits is not a justification for delay. Parties routinely file briefs addressing both non-merits and merits arguments together; otherwise, dispositive motions or even appellate briefs that raise both types of arguments would *always* be bifurcated into separate briefing schedules on staggered timelines. There is even less sense in that piecemeal approach in a case like this one, where time is of the essence due to impending statutory deadlines. Nor are Defendants correct that their approach would serve “judicial economy.” Just the opposite: briefing the merits at the same time as any non-merits issues would not require this Court to *decide* the merits issues if it agreed with Defendants on a threshold, dispositive jurisdictional issue. Simultaneous briefing would simply give this Court the *ability* to reach the merits immediately, thereby avoiding the need for another round of briefing and speeding the ultimate resolution of this important, time-sensitive case—an outcome that is in the public interest regardless of how the Court ultimately rules. Full briefing now would also facilitate swifter appellate review on a more complete record,

should this Court dismiss Plaintiffs' suit, enabling Plaintiffs to seek review of both non-merits and merits issues at the same time—a benefit of critical importance in a case like this one, where the challengers must race against the clock. Defendants' concern about “premature adjudication of constitutional questions” is therefore misplaced.

Second, Defendants' suggestion that Plaintiffs would not be prejudiced by proceeding in piecemeal fashion—which Defendants refer to as the “normal course”—is doubly wrong. As an initial matter, the “normal course” when both parties agree that discovery is unnecessary is to proceed to cross-motions for summary judgment. *See, e.g., Kellogg Co. v. Sabhlok*, 471 F.3d 629, 631 (6th Cir. 2006); *Charter Oaks Fire Ins. Co. v. Clayton*, 62 F.3d 1414 (4th Cir. 1995); *Bajraszewski*, 825 F. Supp. at 877; *Chilcott v. City of Erie*, No. 1:20-CV-289, 2021 WL 4479505, at *1 (W.D. Pa. Sept. 30, 2021); *AstraZeneca Pharms., LP v. Becerra*, No. 1:23-cv-931, Dkt. 15 (D. Del. Sept. 19, 2023). Defendants' refusal to agree to that course here may serve their interest in delaying a resolution on the merits, but it has nothing to do with standard procedure. Furthermore, as discussed above and as Plaintiffs made clear in their amended complaint, they will suffer substantial prejudice from delay due to the burdens of the ongoing “negotiation” process and impending statutory deadlines. *See* Dkt. 57 ¶¶ 36–60. For much the same reason, plaintiffs in other challenges to the IRA around the country have similarly sought to expedite the consideration of their cases on the merits, the government has agreed to schedules that would permit a decision by March 1, 2024, and summary judgment briefing is already well underway in most of the cases. *See, e.g., AstraZeneca Pharms., LP v. Becerra*, No. 1:23-cv-931, Dkt. 15 (D. Del. Sept. 19, 2023); *Boehringer Ingelheim Pharmaceuticals Inc. v. Dep't of Health and Hum. Servs.*, No. 3:23-cv-01103, Dkt. 16 (D. Conn. Sept. 13, 2023); *Bristol-Myers Squibb Co. v. Becerra et al.*, No. 3:23-cv-03335, Dkt. 35 (D.N.J. Oct. 16, 2023); *Janssen Pharmaceuticals Inc. v. Becerra et al.*, No. 3:23-cv-03818, Dkt. 14 (D.N.J. Oct. 16, 2023). Defendants will experience no prejudice from moving this case forward in the same way that many others are moving forward.

Third, while Defendants do not dispute that they can raise any jurisdictional issues they wish in a cross-motion for summary judgment, they express concern that they will be deemed to have waived their venue objections if they do not include them in a document labeled “motion to dismiss.”

But obviously, if the Court grants Plaintiffs' request to proceed to cross-motions for summary judgment and Defendants do so, they will not have waived their venue objections. Waiver must be "knowing, intelligent, and voluntary," *Potee v. Cook*, No. 2:19-CV-5058, 2021 WL 5040257, at *4 (S.D. Ohio Oct. 29, 2021), and parties "d[o] not waive their right[s] . . . simply because they did what the court ordered them to do," *Wiepking v. Prudential-Bache Sec., Inc.*, 940 F.2d 996, 999 (6th Cir. 1991).

Fourth, as discussed above, Defendants' proposal does not reflect "typical practice" in cases where the parties agree that discovery is unnecessary because the case raises only issues of law. Typical practice would be to proceed to cross-motions for summary judgment, as Plaintiffs propose. Defendants cite out-of-circuit cases about prioritizing the adjudication of venue transfer motions, but those cases are inapposite because they suggest only that courts should generally resolve issues of venue before *deciding* the merits, not that courts should avoid ordering simultaneous *briefing* on non-merits and merits issues—especially not in time-sensitive cases like this one where Plaintiffs face a gauntlet of upcoming statutory deadlines. As for Defendants' reliance on the district court's order in the IRA case in the Western District of Texas, that order is inapposite. The plaintiffs in that case filed their motion for summary judgment months ago pursuant to an agreed-upon briefing schedule, and the government's motion to dismiss was fully briefed ten days ago. Here, under Defendants' proposal, their motion to dismiss would not be briefed until *January 21, 2024*, and Plaintiffs would not be permitted to file their summary judgment motion until some unknown time after that. That timeline would cause Plaintiffs' members substantial prejudice because this Court would lack sufficient time to issue a decision on the motion to dismiss, receive briefing on the delayed cross-motions for summary judgment, and issue a decision on the merits until the "negotiation" process is already drawing to a close—if not until after Plaintiffs' members will have already had to "agree" to the "maximum fair price" on August 1, 2024.

At the very least, if the Court decides to order another round of motion-to-dismiss briefing before proceeding to summary judgment, Plaintiffs request that the Court modify Defendants' proposed schedule so that Defendants' motion to dismiss is due by November 6, Plaintiffs' opposition is due by November 20, and Defendants' reply is due by December 1. This Court's September 29,

2023 Order called for Plaintiffs to file an amended complaint by October 13 and for Defendants to file any renewed motion to dismiss by October 27. Plaintiffs filed their amended complaint by October 13 in compliance with that Order, and there is no reason why Defendants cannot file a renewed motion to dismiss (which they acknowledge will include arguments similar to those in their last motion) by November 6—ten days *after* the deadline that the Court set. Plaintiffs respectfully suggest that they have addressed any potential deficiencies in their original complaint, and if this Court determines that sequential briefing is nevertheless appropriate, would ask this Court to approve a schedule that still allows the case to move expeditiously to the merits and permits Plaintiffs to preserve their appellate options before their members are forced to “agree” to government-set prices for their products.

Defendants’ Proposal

Defendants respectfully submit that the scheduling approach contemplated by the Court’s September 29, 2023 opinion—that is, briefing and deciding Defendants’ forthcoming motion to dismiss before moving on to summary-judgment briefing (should summary-judgment briefing ever be necessary)—remains the most efficient way to proceed, for at least four reasons.

First, Defendants intend to raise threshold, non-merits arguments on both jurisdiction and venue—some of which will be similar to arguments that were raised in Defendants’ previous motion to dismiss, some of which will be raised for the first time in response to Plaintiffs’ amended complaint. Should this Court ultimately agree with Defendants that the Southern District of Ohio is an improper venue, or that the Court lacks subject-matter jurisdiction over some or all of Plaintiffs’ claims, then there will be no need to consider the merits at all (or, at a minimum, the case will be narrowed). It serves the interests of efficiency and judicial economy for the Court to first decide whether and to what extent Plaintiffs have filed a viable complaint, before the parties brief the merits—especially where, as here, Plaintiffs bring facial constitutional claims challenging a federal statute. After all, “[s]triking down an Act of Congress ‘is the gravest and most delicate duty that [a federal court] is called on to perform.’” *Shelby Cnty. v. Holder*, 570 U.S. 529, 556 (2013) (quoting *Blodgett v. Holden*, 275 U.S. 142, 148 (1927) (Holmes, J., concurring)). And the Supreme Court has “often stressed the

importance of avoiding the premature adjudication of constitutional questions”—a bedrock principle of judicial restraint that “is applicable to the entire Federal Judiciary, not just to [the Supreme] Court.” *Clinton v. Jones*, 520 U.S. 681, 690 (1997).

Second, proceeding in the normal course—that is, by first briefing and deciding Defendants’ motion to dismiss, and only moving beyond the pleadings stage if necessary—will cause no prejudice to Plaintiffs. Plaintiffs already filed a motion for a preliminary injunction, and requested an expedited decision from this Court by October 1, 2023. This Court denied Plaintiffs’ motion on the timeline that Plaintiffs requested. Although the denial of a motion for a preliminary injunction is immediately appealable as of right, 28 U.S.C. § 1292(a)(1), Plaintiffs have chosen not to appeal, *see* ECF No. 56. Under these circumstances, any delay associated with allowing this litigation to proceed in the normal course is attributable to Plaintiffs’ own decisions about timing and litigation strategy, including Plaintiffs’ choice—unique among the many cases around the country challenging this statute—to begin the litigation by filing a motion for a preliminary injunction. And to the extent that several of Plaintiffs’ arguments rest on the theory that they will suffer irreparable harm during the litigation itself—such that expedited action from this Court is (yet again) necessary—this Court has already *denied* Plaintiffs’ preliminary-injunction motion (in an order that Plaintiffs could have appealed, but decided not to). Plaintiffs will suffer no unfair prejudice in being held to the consequences of their own litigation strategy.

Third, Plaintiffs are incorrect to suggest that all of Defendants’ threshold arguments could be raised in a motion for summary judgment. In particular, Defendants intend to move to dismiss for lack of venue, which may be waived if not included in a Rule 12 motion. *See* Fed. R. Civ. P. 12(h)(1).

Fourth, Defendants’ proposal is more consistent with precedent and typical practice. As courts around the country have recognized, when Defendants seek to transfer or otherwise challenge venue, “disposition of that motion should . . . take[] a top priority in the handling of [a] case.” *In re Horseshoe Ent.*, 337 F.3d 429, 433 (5th Cir. 2003); *accord In re Apple Inc.*, 979 F.3d 1332, 1337 (Fed. Cir. 2020) (“Although district courts have discretion as to how to handle their dockets, once a party files a transfer motion, disposing of that motion should unquestionably take top priority.”); *see also* 5B

Charles Alan Wright & Arthur R. Miller, Federal Practice & Procedure § 1349 (3d ed.) (Rule 12(b) motions “present preliminary or threshold matters that normally should be adjudicated early in the action”). And of course, the Court must resolve the issue of subject-matter jurisdiction before addressing the merits, *Steel Co. v. Citizens for a Better Env’t*, 523 U.S. 83, 101-02 (1998), which is among the reasons why Defendants’ proposal is routine. See, e.g., *Ohio Bell Tel. Co. v. ICG Telecom Grp., Inc.*, No. C2-99-552, 2000 WL 1469356, at *1 (S.D. Ohio Sept. 29, 2000) (approving a “schedule” that “separated jurisdictional issues from the merits of Plaintiffs’ claims,” after “the Magistrate Judge appropriately determined” that all jurisdictional issues had to be addressed first). That is among the reasons why, in the only other lawsuit challenging the Drug Price Negotiation Program that was filed by an association (rather than a pharmaceutical company), a district court in Texas issued an order deciding a similar scheduling dispute in the government’s favor. See Ex. 1, Order, ECF No. 45, *Nat’l Infusion Ctr. Ass’n v. Becerra*, No. 1:23-cv-707 (W.D. Tex.) (granting motion to vacate scheduling order to allow for briefing and decision on the government’s motion to dismiss before allowing any further summary-judgment briefing).

For these reasons, Defendants respectfully request (1) that any summary-judgment briefing be deferred until after the Court has decided Defendants’ motion to dismiss, and (2) that the Court enter the following briefing schedule:

- Defendants’ motion to dismiss: November 22, 2023
- Plaintiffs’ opposition: December 22, 2023
- Defendants’ reply: January 21, 2024

This schedule is reasonable under the circumstances of this case. The faster schedule that Plaintiffs propose (which would have the government’s motion to dismiss due within 14 days of this filing) would be impractical, among other reasons because of pre-existing briefing schedules in other constitutional challenges to the Inflation Reduction Act, and the need for sufficient time for deliberation and review within the government before substantive litigation filings on these important issues of nationwide significance.

8. Recommended date for status conference (if any):

The parties do not believe a status conference is necessary at this time, but can be available at the Court's convenience.

9. Suggestions as to type and timing of efforts at Alternative Dispute Resolution:

The parties do not believe this case is a good candidate for Alternative Dispute Resolution, because Plaintiffs bring a facial constitutional challenge to a federal statute.

10. Recommended date for a final pretrial conference:

The parties do not believe that the Court needs to set a date for a final pretrial conference at this time, because the case can and should be resolved via dispositive motion(s).

11. Has a settlement demand been made? No.

12. Other matters pertinent to scheduling or management of this litigation:

The parties agree that, regardless of how the Court resolves the scheduling dispute above, the Court should dispense with Defendants' obligation (if any) to file an answer to the amended complaint. Given the nature of Plaintiffs' facial constitutional claims, an answer would not promote the efficient resolution of this litigation.

Dated: October 23, 2023

Respectfully submitted,

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