UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
AMARILLO DIVISION

Alliance for Hippocratic Medicine, *et al.*, Plaintiffs, *v.* U.S. Food and Drug Administration, *et al.*, Defendants.	Case No. 2:22-cv-00223-Z

Defendants' Response to Order Proposing Advancement of
Trial on the Merits and Consolidation with Preliminary-Injunction Hearing

The Court has ordered the parties to brief whether a trial on the merits should be advanced and consolidated with a hearing on Plaintiffs' Motion for Preliminary Injunction under Federal Rule of Civil Procedure 65(a)(2). ECF No. 32. Defendants respectfully respond to explain why advancing a trial on the merits would be improper.

Both the Supreme Court and the Fifth Circuit have explained that accelerating a trial on the merits under Rule 65(a)(2) is "generally inappropriate." *Univ. of Tex. v. Camenisch*, 451 U.S. 390, 395 (1981); *H & W Indus., Inc. v. Formosa Plastics Corp., USA*, 860 F.2d 172, 176 (5th Cir. 1988) (quoting *Camenisch*, 451 U.S. at 395). That is especially true under the circumstances of this case. Given Plaintiffs' failure to demonstrate irreparable harm (or, indeed, *any* harm) flowing from mifepristone's[1] continued marketing, *see* Defs.' PI Opp'n (ECF No. 28) at 8-15, 31-33, coupled with their extreme delay in filing suit to challenge FDA's approval of the drug, there is no reason to decide this case on an emergency basis. Moreover, it is black-letter law that an Administrative Procedure Act (APA) case like this one must be decided not at trial, but on the basis of the full administrative record supporting the agency's decisions. In this case, there is every

[1] This brief uses "mifepristone" to refer to drug products that are approved for medical termination of early pregnancy, in both branded and generic form.

reason to follow the ordinary procedural course, including the consideration of a motion to dismiss that would narrow any issues that might need to be addressed on the merits, and thus the scope of the administrative records, which would presently span six different agency actions. Indeed, the parties' joint scheduling motion contemplated a normal briefing schedule after the conclusion of preliminary-injunction proceedings that would allow the Court to assure itself of jurisdiction before deciding the merits, *see* Joint Sched. Mot. (ECF No. 12) at 2 ("Within two weeks of this Court's ruling on Plaintiffs' [Preliminary-Injunction] Motion, the parties will propose a new answer or response deadline."), and the Court adopted that proposal, *see* Order (ECF No. 13).

Accordingly, the Court should deny Plaintiffs' preliminary-injunction motion or hold it in abeyance, then direct the parties to confer and propose within ten days a schedule for the briefing of a motion to dismiss and, if that motion is denied in whole or in part, production of the administrative records for any remaining claims and cross-motions for summary judgment.

I. Acceleration of a Determination on the Merits Under Rule 65(a)(2) Is Generally Inappropriate, and This Case Warrants No Exception.

Federal Rule of Civil Procedure 65(a)(2) provides a mechanism, in limited circumstances, for acceleration of a trial on the merits: "Before or after beginning the hearing on a motion for a preliminary injunction, the court may advance the trial on the merits and consolidate it with the hearing." But both the Supreme Court and the Fifth Circuit have cautioned that "it is generally inappropriate for a federal court at the preliminary-injunction stage to give a final judgment on the merits" using this procedure. *Camenisch*, 451 U.S. at 395; *H & W Indus.*, 860 F.2d at 176. This is because a preliminary-injunction motion is often decided in "haste" and is intended for the "limited purpose" "merely to preserve the relative positions of the parties until a trial on the merits can be held." *Camenisch*, 451 U.S. at 395. Furthermore, preliminary proceedings typically are "granted on the basis of procedures that are less formal and evidence that is less complete than in a trial on the merits." *Id*. That certainly is true in this case, where the preliminary-injunction record contains only excerpts from the underlying administrative proceedings, rather than the complete

administrative record supporting the challenged actions—multiple records spanning decades of agency decisionmaking.

As a leading treatise explains, "the Supreme Court has cautioned that although consolidation may be used to real advantage in some cases, it generally is inappropriate." 11A Charles A. Wright & Arthur R. Miller, Federal Practice & Procedure § 2590 (3d ed.). The Fifth Circuit agrees. *See, e.g.*, *H & W Indus.*, 860 F.2d at 176 (quoting *Camenisch*, 451 U.S. at 395). At a minimum, "[c]onsolidation cannot be ordered by the court without adequate notice and an opportunity for a full hearing on the merits." *Am. Fed'n of Gov't Emp., AFL-CIO, Loc. 3319, U.S. Deputy Marshals v. Colburn*, 531 F.2d 314, 315 (5th Cir. 1976); *see also, e.g.*, *Wohlfahrt v. Mem'l Med. Ctr.*, 658 F.2d 416, 418 (5th Cir. 1981) ("[S]ufficient notice is required to permit the parties to develop their cases fully.").

Consolidation under Rule 65(a)(2) may be appropriate when "a real exigency has been shown that justifies giving the case preference over other disputes that already are on the docket." 11A Charles A. Wright & Arthur R. Miller, Federal Practice & Procedure § 2590 (3d ed.); *accord Kickapoo Traditional Tribe of Tex. v. Chacon*, 46 F. Supp. 2d 644, 648-49 (W.D. Tex. 1999) (listing "exigent circumstances" as one factor to consider); *Morris v. District of Columbia*, 38 F. Supp. 3d 57, 63 (D.D.C. 2014) (same); *Zucker v. Menifee*, No. 03-cv-10077, 2004 WL 102779, at *2 (S.D.N.Y. Jan. 21, 2004) (same). Other considerations include whether "the relevant facts are undisputed," *Kickapoo Tribe*, 46 F. Supp. 2d at 648-49, and whether "[c]ombining the trial and the Rule 65(a) hearing avoids having the same evidence presented both at the preliminary injunction stage and later at trial," 11A Charles A. Wright & Arthur R. Miller, Federal Practice & Procedure § 2590 (3d ed.).

Far from warranting any exception to the general rule, this case would be particularly inappropriate for an accelerated determination on the merits. First, for the very reason that Plaintiffs fail to demonstrate irreparable harm warranting preliminary relief here, there are no "exigent circumstances" whatsoever. *Kickapoo Tribe*, 46 F. Supp. 2d at 648-49. Mifepristone was first approved nearly twenty-three years ago, yet Plaintiffs waited years to file suit to challenge its

approval. ECF No. 1, Compl. (filed Nov. 18, 2022). Even the most-recent action about which Plaintiffs complain occurred in December 2021, nearly a full year before they filed suit. In sum, given Plaintiffs' extraordinary delay in mounting this challenge, and particularly in light of their failure to demonstrate any irreparable harm (let alone irreparable harm *to themselves*) while mifepristone remains in use by other physicians, this plainly is not a case in which "a real exigency has been shown that justifies giving the case preference over other disputes that already are on the docket." 11A Charles A. Wright & Arthur R. Miller, Federal Practice & Procedure § 2590 (3d ed.); *see also* Defs.' PI Opp'n at 31-32 (collecting cases and arguing that Plaintiffs' delay undermines any claim to imminent irreparable harm).

Second, the nature of the decisions at issue further weighs against unusual expedition. Plaintiffs raise numerous theories, including novel claims second-guessing FDA's safety and efficacy determinations, and seek an order that would withdraw from the market a drug that has been widely available for more than two decades. *See* Defs.' PI Opp'n at 31 (explaining that no court has upended an FDA drug approval under similar circumstances). Although these claims lack merit for myriad reasons, including but not limited to those set forth in Defendants' preliminary-injunction opposition, ECF No. 28, the parties' arguments certainly deserve careful consideration and thorough analysis, rather than an unnecessarily rushed presentation by the parties.

Third, this is not a case where the issues are teed up through undisputed facts or where consolidation would avoid duplicative presentation of evidence at the preliminary-injunction hearing and the merits stage of the proceedings. *See Kickapoo Tribe*, 46 F. Supp. 2d at 648-49. Plaintiffs' claims arise under the APA and must therefore be decided on the full administrative records before the agency when it took the challenged actions. *See infra* Part II. Consolidating Plaintiffs' preliminary-injunction motion with a merits ruling at this time would not promote efficiency because the merits of Plaintiffs' claims are inappropriate for resolution either based on the preliminary-injunction record or through trial (or presentation of disputed facts at any stage). *See, e.g.*, *Camp v. Pitts*, 411 U.S. 138, 142 (1973) (in APA cases, "the focal point for judicial

review should be the administrative record already in existence, not some new record made initially in the reviewing court"). The case should thus proceed in the normal course, with fulsome briefing on a full record.

In sum, none of the factors that might justify deviating from the normal course of litigation and invoking Rule 65(a)(2)'s disfavored procedures is present here.

II. Accelerating a Determination on the Merits Would Substantially Prejudice Defendants.

In any event, the Court cannot properly reach the merits of the claims in this case in the absence of the full administrative record for each challenged decision. Plaintiffs' complaint presents an incomplete picture of FDA's decisions and the evidence on which they were based, including many allegations that are squarely disputed and can be evaluated only through a review of the actual, full administrative records of those decisions. *See* Compl. ¶¶ 118-254. Indeed, Plaintiffs allege that FDA's challenged actions were "unreasonable and unsupported by the evidence and information considered by the agency at the time of its decisionmaking." Compl. ¶¶ 364, 401 (challenging FDA's responses to Plaintiffs' citizen petitions); *see also, e.g.*, *id.* ¶¶ 341-44 (challenging FDA's alleged "fail[ure] to perform a statistical analysis" and "impermissibly extrapolated conclusions about the safety and effectiveness of mifepristone" when it granted approval in 2000). And even with respect to Plaintiffs' claims alleging supposed legal errors by the agency, the administrative records could provide important insight into the extent to which the agency considered and resolved such issues, and how the agency understood its overall regulatory authority in light of those issues. *See, e.g.*, *Robinson v. Veneman*, 124 F. App'x 893, 895 (5th Cir. 2005) (explaining that the "administrative record is also reviewed to determine whether the challenged action was 'contrary to constitutional right, power, privilege, or immunity'" (quoting 5 U.S.C. § 706(2)(B))). Consolidation would deprive Defendants of the opportunity to present more-fulsome briefing on such issues based on the agency's justifications in the full administrative records.

The complete administrative records are therefore an essential prerequisite to any decision on the merits by this Court. Judicial review is based upon the "full administrative record that was before [the agency] at the time [it] made [its] decision," *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 420 (1971), *abrogated on other grounds by Califano v. Saunders*, 430 U.S. 99 (1977), and "meaningful judicial review" must be based on the "agency's contemporaneous explanation" presented in the administrative record, *Department of Commerce v. New York*, 139 S. Ct. 2551, 2573 (2019). Indeed, the APA statutorily requires that any final decision on the merits be based on the full administrative record, or at least that the parties have the full record before them. *See* 5 U.S.C. § 706 ("In making the foregoing determinations, the court *shall* review the whole record or those parts of it cited by a party[.]" (emphasis added)). The record currently before the Court contains only excerpts, however, from the universe of materials that likely would constitute the full administrative records. Once compiled and certified by the agency, the complete administrative records would include additional information supporting the agency's decisions, and it is those records that must form the basis of review of these important agency actions affecting hundreds of thousands of Americans each year. Proceeding to final judgment on the merits *without* allowing Defendants to produce and present argument based on the administrative records would fall short of the process necessary to allow Defendants fully to present their case, particularly where the only briefing has taken place on a compressed preliminary-injunction timeline.

Moreover, consolidation would deprive Defendants of their ability to file a motion to dismiss raising issues that were unnecessary for resolution of Plaintiffs' preliminary-injunction motion, as anticipated by the parties' joint scheduling motion. For instance, Defendants should be afforded the opportunity to file a motion to dismiss for improper venue, on the ground that Plaintiffs have failed to establish standing for any Plaintiff located in this district. Defendants would be prejudiced by being denied the opportunity to raise such issues, given that Plaintiffs wholly failed to establish irreparable harm or to offer any legitimate basis to upend the longstanding status quo through emergency preliminary relief. And there is no reason to rush to

judgment in this case in light of Plaintiffs' extreme delay in bringing their claims, the extraordinary and unprecedented nature of the relief they seek, the absence of showing of any harm (let alone irreparable harm) to Plaintiffs, and the substantial harm that would befall physicians who prescribe, patients who use, and companies who hold the approved applications for mifepristone and could be blindsided by any ruling in Plaintiffs' favor.

III. The Court Should Deny Plaintiffs' Motion or Hold It in Abeyance, and Direct the Parties to Confer and Propose a Schedule for Further Proceedings.

Given that this is not the rare case in which invoking Rule 65(a)(2) is appropriate and that Plaintiffs have failed to show irreparable harm absent the requested extraordinary relief, this litigation should follow the ordinary procedural course: The preliminary-injunction motion should be denied or, at minimum, held in abeyance; FDA should have the opportunity to file a motion to dismiss that would narrow any issues that might need to be addressed on the merits, just as the parties contemplated in their joint scheduling proposal and the Court endorsed in its scheduling order; and, if Plaintiffs demonstrate standing to raise challenges to any agency decisions that are exhausted and not time-barred, FDA should be afforded a reasonable time to compile and certify the administrative records, and the parties should be provided an opportunity to brief cross-motions for summary judgment.

The practical importance of narrowing the scope of this case through ordinary motion-to-dismiss briefing bears emphasis here. Plaintiffs challenge no fewer than six distinct agency actions spanning more than two decades, and many of those challenges fail for threshold reasons. *See* Defs.' PI Mot. at 8-20. Thus, until this Court resolves these threshold issues—which Defendants previewed in their preliminary-injunction opposition and intend to press in more fulsome fashion in their motion to dismiss—"the time of the court should not be occupied with any further proceeding." *See United Transp. Serv. Employees of Am., CIO v. Nat'l Mediation Bd.*, 179 F.2d 446, 454 (D.C. Cir. 1949). Moreover, the potential burden on FDA of assembling administrative records for up to six discrete actions should not be underestimated. These records collectively are

likely to span tens—if not hundreds—of thousands of pages. Approximately 750 volumes of documents associated with the mifepristone new drug approval are in hard copy, nearly two-thirds of which are stored in an off-site federal record center. They must be retrieved and scanned before FDA could begin to identify precisely which documents correspond with the relevant decisions. FDA would then need to review the record documents retrieved from the archives, alongside records stored at the agency in electronic form, on a careful, page-by-page basis to redact protected information, including, for example, confidential commercial information—which FDA is bound to protect, and which it is well established does not necessarily form a part of the record for review, *see, e.g.*, *Flyers Rts. Educ. Fund, Inc. v. Fed. Aviation Admin.*, 864 F.3d 738, 745-46 (D.C. Cir. 2017); *MD Pharm., Inc. v. Drug Enforcement Admin.*, 133 F.3d 8, 13 (D.C. Cir. 1998); 21 C.F.R. § 20.61.

As a result, it will doubtless take significant time and resources to retrieve and assemble these records, an exercise that the agency reasonably has not undertaken at this preliminary stage of the case, given that the need to do so could be obviated, in whole or in part, by resolution of Defendant's threshold arguments. Narrowing the scope of this case would thus allow the agency to focus its efforts and more quickly assemble and review the records for any claims that might reach merits proceedings.

IV. A Trial Is Not Appropriate Because Plaintiffs' Claims Must Be Decided on the Administrative Record.

To the extent the Court disagrees with Defendants' position and intends nonetheless to consolidate and enter final judgment, consolidation would not warrant moving forward with a "trial on the merits," ECF No. 32, or any other judicial factfinding inquiry. This case would remain one arising under the Administrative Procedure Act, and therefore "the focal point for judicial review should be the administrative record already in existence, not some new record made initially in the reviewing court." *Camp v. Pitts*, 411 U.S. 138, 142 (1973) (per curiam); *see also*

Fla. Power & Light Co. v. Lorion, 470 U.S. 729, 743 (1985). Any contrary procedure would conflate the respective roles of the agency and the Court in APA cases.

"Under the APA, it is the role of the agency to resolve factual issues to arrive at a decision that is supported by the administrative record." *Hi-Tech Pharmacal Co. v. FDA*, 587 F. Supp. 2d 13, 18 (D.D.C. 2008) (citation omitted). "[T]he district judge," in turn, "sits as an appellate tribunal," *Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1083 (D.C. Cir. 2001), because "the function of the district court is to determine whether or not as a matter of law the evidence in the administrative record permitted the agency to make the decision it did." *City & Cty. of San Francisco v. United States*, 130 F.3d 873, 877 (9th Cir. 1997) (quotation omitted). "The entire case on review is a question of law, and only a question of law," *Policy & Research, LLC v. HHS*, 313 F. Supp. 3d 62, 74 (D.D.C. 2018) (quotation omitted), and "summary judgment is the proper mechanism for deciding, as a matter of law, whether an agency action is supported by the administrative record and consistent with the APA standard of review," *Lannett Co., Inc. v. FDA,* 300 F. Supp. 3d 34, 41 (D.D.C. 2017). Deciding this case at a "trial on the merits," rather than through cross-motions for summary judgment, would not only distort this Court's defined role as a court of review—rather than a finder of fact—in APA cases, but also risk exceeding the proper scope of its review, which is confined to assessing the rationality of FDA's decisions based on the record before the agency when those decisions were made. *See, e.g.*, *CTS Corp. v. EPA*, 759 F.3d 52, 64 (D.C. Cir. 2014) ("It is black-letter administrative law that in an [APA] case, a reviewing court should have before it neither more nor less information than did the agency when it made its decision."); *San Luis Obispo Mothers for Peace v. NRC*, 751 F.2d 1287, 1325 (D.C. Cir. 1986) (en banc) (noting that the record-review rule assures that, in APA cases, "the agency and not the court is the principal decision maker," and discourages courts from "cavalierly … supplement[ing] the record … in the belief that they were better informed than the administrators empowered by Congress").

Moreover, before entering any final judgment, the Court should provide the parties an opportunity to address the appropriate scope of any remedy—an issue that was not ripe for the

parties to address in their preliminary-injunction briefing, but that would be a natural part of any eventual summary-judgment briefing.

Finally, consolidation and entry of final judgment would not avoid this Court's obligation to carefully consider the equities and the public interest, since those factors would be relevant to any permanent injunction. In addition, to the extent that the Court issues an adverse judgment or injunction, the government hereby requests that any such judgment or injunction be stayed pending any appeal that is authorized and pursued. *See generally Nken v. Holder*, 556 U.S. 418, 421 (2009) ("[I]t has always been held that as part of its traditional equipment for the administration of justice, a federal court can stay the enforcement of a judgment pending the outcome of an appeal. A stay does not make time stand still, but does hold a ruling in abeyance to allow an appellate court the time necessary to review it."). The basis for this stay request is already amply set forth in Defendants' preliminary-injunction opposition, ECF No. 28 at 38-40, detailing the numerous harms that would stem from upending the status quo and abruptly withdrawing mifepristone from the market. *See, e.g.*, *Barber v. Bryant*, 833 F.3d 510, 511 (5th Cir. 2016) ("[T]he maintenance of the status quo is an important consideration in granting a stay."). At a minimum, if the Court were to enter an adverse judgment, the government respectfully requests that the Court enter a short administrative stay of 21 days to allow the government time to seek an emergency, expedited stay from the court of appeals if an appeal is authorized.

CONCLUSION

The Court should deny Plaintiffs' preliminary-injunction motion or hold it in abeyance and direct the parties to confer and propose within ten days a schedule for the briefing of a motion to dismiss and, if that motion is denied in part, production of the administrative records and cross-motions for summary judgment.

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