



contentions that FDA “disavow[ed] science,” “ignored” impacts of mifepristone, “disregarded” evidence before it, and made changes that “failed to satisfy the rigorous scientific standards” of the Federal Food, Drug, and Cosmetic Act. *See, e.g.*, Compl., ECF No. 1, ¶¶ 9, 16. They further allege that FDA acted without “substantial evidence,” relied on inadequate or flawed studies, and exercised its agency expertise in evaluating studies and data in ways that Plaintiffs disagree with. *E.g., id.* ¶¶ 200-205, 341-344. Any evaluation of the merits (or lack thereof) of these allegations requires a full understanding of the agency’s application of its expertise to the facts and evidence that were before it. As a result, no judicial determination of the merits can properly occur without consideration of the full administrative record. Unless and until the full administrative record is available to the parties and the Court, Danco opposes any consideration of the merits.

**1. No merits ruling can properly issue based only on the preliminary injunction record currently before the Court.**

The record currently before the Court consists of bits and pieces of evidence that the parties have provided. It does not contain the entire record of more than two decades of agency review, analysis, and approvals related to mifepristone. As a result, any ruling beyond the preliminary injunction motion would be premature; it would not be properly based on the full picture of FDA’s consideration of the risks and benefits of mifepristone and could not demonstrate whether FDA acted arbitrarily and capriciously in its consideration of the safety and effectiveness of this product.

The Fifth Circuit has explained that, when a preliminary injunction is consolidated with the merits, a party “must have an opportunity to present additional material and arguments” before a merits ruling issues. *Underwood v. Hunter*, 604 F.2d 367, 369 (5th Cir. 1979) (per curiam). Indeed, because “the issues which are considered in the preliminary injunction hearing are entirely different from the focus of a summary judgment adjudication,” it is particularly “risky . . . to assume that the often incomplete evidence adduced at a preliminary injunction hearing is sufficient

to determine whether a claimant is entitled to judgment as a matter of law.” *H & W Indus., Inc. v. Formosa Plastics Corp., USA*, 860 F.2d 172, 177 (5th Cir. 1988) (internal quotation marks omitted); accord 11A Charles Alan Wright, Arthur R. Miller & Mary Kay Kane, *Federal Practice and Procedure: Civil* § 2950 (3d ed. 2022 update). That is especially true in APA cases where the agency is responsible for filing the full administrative record, meaning the preliminary injunction record is necessarily incomplete. *See infra* p. 5 (detailing information missing from existing record).

Not only is the existing record underinclusive when it comes to the merits, it is also impermissibly overinclusive; it contains irrelevant extra-record evidence proffered by Plaintiffs that was *not* before FDA when it rendered the challenged decisions. *See* Danco Opp’n to Mot. for Prelim. Inj., ECF No. 50, at 24. To the extent that Plaintiffs’ amici similarly invoke extra-record evidence throughout their briefs, that material is likewise not a basis for a ruling on the merits of FDA’s approvals in this case. Judicial review in agency cases focuses on the existing administrative record, “not some new record made initially in the reviewing court.” *Fla. Power & Light Co. v. Lorion*, 470 U.S. 729, 743 (1985) (internal quotation marks omitted). A merits decision on the existing record would be improper.

Finally, it would be highly unusual to convert the preliminary injunction hearing to a merits trial at this stage of the briefing process where one party opposes doing so on a more limited record. *See, e.g., Puerto Rican Farm Workers ex rel. Vidal v. Eatmon*, 427 F.2d 210 (5th Cir. 1970) (per curiam) (vacating denial of permanent injunction where party did not consent to consolidation on a more limited record because the court effectively denied the party “a full hearing on the merits”). *Cf., e.g., John v. State of La. (Bd. of Trs. for State Colls. & Univs.)*, 757 F.2d 698, 704 (5th Cir.

1985) (“the parties are certainly free to agree to submission of a case for final resolution on a limited or stipulated record”).

For all these reasons, the Court cannot rely on the existing preliminary injunction record to render a decision on the merits.

**2. If the Court proceeds on a full administrative record and allows briefing by the parties based on the full administrative record, Danco supports consolidating the preliminary injunction hearing and a trial on the merits.**

As this Court recently explained, “[i]n judicial review of agency action, the focal point . . . should be the administrative record the agency presents to the reviewing court.” *Texas v. Biden*, No. 2:21-CV-067-Z, 2021 WL 4552546, at \*2 (N.D. Tex. June 7, 2021) (Kacsmayk, J.) (internal quotation marks and alteration omitted); *accord Fla. Power & Light Co.*, 470 U.S. at 743-744. That is because, under the APA, judicial “review is to be based on the full administrative record that was before the Secretary at the time he made his decision.” *Citizens to Pres. Overton Park, Inc. v. Volpe*, 401 U.S. 402, 420 (1971), *abrogated on other grounds by Califano v. Saunders*, 430 U.S. 99 (1977); *accord, e.g., Dep’t of Commerce v. New York*, 139 S. Ct. 2551, 2573 (2019) (“meaningful judicial review” must be based on “the agency’s contemporaneous explanation in light of the existing administrative record”).

Here, “the inclusion of the administrative record will provide a firm basis for the Court’s analysis of Plaintiffs’ APA claims.” *Texas*, 2021 WL 4552546, at \*2. This case involves a complex series of FDA actions spanning more than two decades. Each of Plaintiffs’ claims arises under the APA. Compl., ECF No. 1, at 94-110 (Claims for Relief). And each claim asks the Court to evaluate FDA’s reasoning underlying its administrative decisions, and contends that FDA’s rationale was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. *See id.*; *see also* Pls.’ Br. in Supp. of Mot. for Prelim. Inj., ECF No. 7, at 13-23.

Danco and Plaintiffs agree that the Court cannot apply that standard without evaluating the full administrative record that details the basis for FDA's decisions. *See* ECF No. 68; *see, e.g., Fla. Power & Light Co.*, 470 U.S. at 743-744. The administrative record undoubtedly contains additional, highly relevant material that will bear on Plaintiffs' merits arguments. For example, the preliminary injunction record does not contain the March 14, 1996 New Drug Application (NDA); Danco's September 17, 2008 Risk Evaluation and Mitigation Strategies (REMS) application; Danco's November 4, 2015 Supplemental New Drug Application (sNDA); or Danco's March 15, 2021 sNDA. It also does not include communications between the sponsor and FDA on any number of substantive issues relevant to how the sponsor demonstrated the product's safety and effectiveness, or internal FDA documents reflecting discussion within the agency related to the decisions to approve the NDA, sNDAs, or REMS. These submissions and documents provide the basis for this Court to evaluate whether FDA's approval decisions were arbitrary and capricious. Without them, the Court is unable to fully evaluate whether FDA's decisions were reasoned and supported.

**3. To the extent there are disputes about the contents of the administrative record, including potential redactions, those should be resolved in advance of summary judgment briefing.**

The Court should not order FDA to produce an unredacted administrative record in the first instance. *See* ECF No. 68 at 7. There are many situations in which it is appropriate to redact information in an administrative record. For example, agencies may redact personal information, such as names and contact information. *See, e.g., Ethridge v. Am. Airlines, Inc.*, No. 5:05-CV-630-H(2), 2006 WL 8438791, at \*1 (E.D.N.C. Nov. 6, 2006) (ordering agency to redact plaintiff's "sensitive and confidential personal information" from the administrative record). The agency or entity named in an administrative record may seek to have information redacted as confidential

business information. *See, e.g., Silvertown Mountain Guides LLC v. U.S. Forest Serv.*, No. 3:22-CV-00048-HRH, 2022 WL 16553223, at \*4 (D. Alaska Oct. 31, 2022). Or the agency may assert that certain documents are protected by attorney-client privilege, work product doctrine, or deliberative process privilege. *See, e.g., United States v. Colliot*, No. AU-16-CA-01281-SS, 2017 WL 6348129, at \*3 n.4 (W.D. Tex. Dec. 15, 2017) (“[a] complete administrative record . . . does not include privileged materials” (internal quotation marks omitted)). Whether these redactions are appropriate is impossible to decide in the abstract. To the extent Plaintiffs suggest otherwise and ask the Court to order FDA to produce an unredacted version of the administrative record in the first instance, *see* ECF No. 68 at 6-7, the Court should deny that premature request.

Moreover, for the same reasons the Court cannot resolve the merits based on an incomplete administrative record, the parties cannot effectively brief the merits based on an incomplete administrative record. *Supra* pp. 4-5. Thus, insofar as there are disputes over the contents of the administrative record, including disputes about the inclusion of any extra-record materials, they must be resolved before the parties proceed to dispositive briefing.

As commonly occurs in APA cases, if the Court proceeds with obtaining the administrative record, the parties could propose a schedule for expedited briefing based on that record in order to efficiently move this case forward. *See, e.g., Red Lake Band of Chippewa Indians v. U.S. Army Corps of Eng’rs*, No. CV 20-3817 (CKK), 2021 WL 430054, at \*7 (D.D.C. Feb. 7, 2021); *Amgen Inc. v. Hargan*, 285 F. Supp. 3d 351, 363 (D.D.C. 2018).

As an additional matter of efficiency, Danco respectfully suggests that while the administrative record is being prepared, the Court could resolve any motions to dismiss based on threshold legal defects, such as lack of standing and statute of limitations, that do not depend on the administrative record. *See, e.g., Texas*, 2021 WL 4552546, at \*1 (noting that, without

jurisdiction, “the Court is without power to advance to the merits”). If necessary, the Court could then proceed to trial on the merits once the administrative record is available.

If the Court consolidates the preliminary injunction with the merits, Danco proposes that the Court allow the parties five business days to consult and propose a joint briefing schedule, including the date for production of the administrative record; dates for briefing any disputes concerning the contents of the administrative record, including potential redactions and extra-record materials; and dates for the parties’ dispositive briefs and an accompanying hearing.

**CONCLUSION**

For the foregoing reasons, Danco supports combining the injunction hearing with a merits trial on the full administrative record.

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Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I certify that on February 10, 2023, I electronically filed the foregoing Supplemental Brief using the CM/ECF system. Notice of this filing will be sent by operation of the Court's electronic filing system to all parties of record.

/s/ Jessica L. Ellsworth