

UNITED STATES DISTRICT COURT
DISTRICT OF MARYLAND

AMERICAN COLLEGE OF
OBSTETRICIANS AND
GYNECOLOGISTS, *on behalf of its members
and members' patients*,
COUNCIL OF UNIVERSITY CHAIRS OF
OBSTETRICS AND GYNECOLOGY, *on
behalf of its members and members' patients*,
NEW YORK STATE ACADEMY OF
FAMILY PHYSICIANS, *on behalf of its
members and members' patients*,
SISTERSONG WOMEN OF COLOR
REPRODUCTIVE JUSTICE COLLECTIVE,
*on behalf of its members and members'
patients*, and
HONOR MACNAUGHTON, M.D.,

Plaintiffs,

v.

UNITED STATES FOOD AND DRUG
ADMINISTRATION,
STEPHEN M. HAHN, M.D., *in his official
capacity as Commissioner of Food and Drugs,
and his employees, agents and successors in
office*,
UNITED STATES DEPARTMENT OF
HEALTH AND HUMAN SERVICES and
ALEX AZAR, J.D., *in his official capacity as
Secretary, United States Department of
Health and Human Services, and his
employees, agents and successors in office*,

Defendants.

Civil Action No. TDC-20-1320

ORDER

Pending before the Court is Plaintiffs' Motion for Clarification, ECF No. 109, in which it seeks clarification of the Court's July 13, 2020 Preliminary Injunction relating to the United States

Food and Drug Administration (“FDA”) Risk Evaluation and Mitigation Strategies (“REMS”) applicable to mifepristone in which the Court temporarily barred the enforcement of the REMS in-person dispensing requirement for mifepristone during the COVID-19 pandemic. Plaintiffs seek a modification or clarification of the Preliminary Injunction to permit certified healthcare providers to contract with mail-order pharmacies to stock mifepristone and deliver it to patients only at the direction and under the supervision of the prescribing healthcare provider. Defendants argue that the Court lacks jurisdiction to consider the Motion because they have filed a notice of appeal of the Preliminary Injunction, and the matter is therefore before the United States Court of Appeals for the Fourth Circuit.

“Generally, a timely filed notice of appeal transfers jurisdiction of a case to the court of appeals and strips a district court of jurisdiction to rule on any matters involved in the appeal.” *Doe v. Pub. Citizen*, 749 F.3d 246, 258 (4th Cir. 2014); see *Griggs v. Provident Consumer Disc. Co.*, 459 U.S. 56, 58 (1982). One narrow exception to this rule is when an action by the district court “aids the appellate process.” *Pub. Citizen*, 749 F.3d at 258. For example, under this exception, a district court may modify the ruling on appeal to clarify it in a way that would relieve the appellate court from needing to address an issue “begotten merely from imprecise wording” in the appealed order. *Lytle v. Griffith*, 240 F.3d 404, 407 n.2 (4th Cir. 2001) (holding that the district court had jurisdiction to modify its injunction order while it was on appeal to clarify the meaning of the term “the Commonwealth” used in the memorandum opinion but not defined in the injunction order). In *Dixon v. Edwards*, 290 F.3d 699 (4th Cir. 2002), the Fourth Circuit concluded that, during the pendency of an appeal, the district court properly could clarify an injunction barring an individual from “officiat[ing] at religious services on or near the grounds” of a church by issuing a modification order stating that the same individual “shall be permitted to conduct

religious services at least 300 feet distant from the perimeter” of the church. *Id.* at 709 & n.14. Here, Plaintiffs seek a modification or clarification comparable to the requests in *Dixon* and *Lytle* because they seek clarification of the scope of the Court’s Preliminary Injunction in light of a potential inconsistency between the language of the Preliminary Injunction and that of the accompanying Memorandum Opinion. Because such a clarification would be “in aid of the appeal” by more definitively delineating the terms of the Preliminary Injunction, the Court may rule on the Motion. *Dixon*, 290 F.3d at 709 n.14.

The Court clarifies its July 13, 2020 ruling by stating that the Preliminary Injunction, ECF No. 92, is the Court’s Order defining the terms of the preliminary injunction it granted, and the language in that Order controls over any particular language in the accompanying Memorandum Opinion, ECF No. 90. *See Dixon*, 290 F.3d at 720 (in considering a discrepancy between an order and an opinion, stating that “the language of the . . . Order is controlling, because courts speak through their orders”). On the issue of whether a mail-order pharmacy may be used as part of the distribution chain, the Preliminary Injunction provides that it bars enforcement of the Element to Assure Safe Use set forth in 21 U.S.C. § 355-1(f)(3)(C) “only to the extent that it requires that mifepristone be dispensed only in clinics, medical offices, or hospitals, rather than by mail or delivery service” and that “[d]ispensing by mail or delivery service must still occur by or under the supervision of a certified healthcare provider.” Prelim. Inj. at 2. This requirement that dispensing by mail or delivery service remain “by or under the supervision of a certified healthcare provider” permits mifepristone to be sent from a drug sponsor to a certified healthcare provider in the care of a mail-order pharmacy if the pharmacy has a contractual agreement with the certified healthcare provider to receive mifepristone on behalf of the healthcare provider and then to mail the drug to a patient at the direction of that healthcare provider, so long as the drugs were

specifically ordered from the drug sponsor by the certified healthcare provider and held on the provider's behalf, and the mail-order pharmacy has no right to distribute those drugs except at the direction of the certified healthcare provider. Where neither drug sponsors nor mail-order pharmacies are parties to this case, whether a drug sponsor and a mail-order pharmacy may, consistent with the REMS, enter into their own contract to ship mifepristone to a mail-order pharmacy absent actual orders from certified healthcare providers is not an issue properly before the Court, but it is not conduct protected by the Preliminary Injunction.

The Court declines to amend the Memorandum Opinion both because it is the language of the Preliminary Injunction which controls and because the arguably conflicting language of the Memorandum Opinion is not actually inconsistent. As to the language stating that "the drug sponsor must still ensure that mifepristone is 'not distributed through retail pharmacies'" and that "the drug will still have to be distributed first to certified healthcare providers who then must arrange for the mailing or delivery of the mifepristone," Mem. Op. at 80, the Court notes that under the above-described arrangement, the drug would still be distributed first to the certified healthcare provider when it is sent to that provider's own account at a mail-order pharmacy. Where the mail-order pharmacy would simply be an agent storing product on behalf of the healthcare provider and mailing the drug under the supervision of the healthcare provider, and it would report the serial numbers to the certified healthcare provider, it would not be acting as a retail pharmacy. In this regard, the arrangement does not conflict with the Court's statements that certified healthcare providers must "still comply with all other REMS requirements" and that the Court "is not barring the enforcement of other REMS requirements not dependent on an in-person patient visit." Mem. Op. at 79.

As for the language on page 58 of the Memorandum Opinion noting that “healthcare providers would be able to choose the most efficient means of getting the drug from their office to their patient under the existing circumstances,” that language related to a discussion of the limited benefits of the in-person dispensing requirement, not a description of the specific terms of the Preliminary Injunction. The language addressed a scenario in which a certified healthcare provider had mifepristone in the provider’s medical office and was not intended to, and does not, impose any requirement that mifepristone physically pass through a medical office or otherwise define the parameters of the Preliminary Injunction.

Accordingly, it is hereby ORDERED that the Motion for Clarification, ECF No. 109, is GRANTED IN PART and DENIED IN PART. The Motion is granted to the extent that the Court clarifies that the language of the Preliminary Injunction controls over the language of the Memorandum Opinion and therefore permits the distribution arrangement described above. The Motion is denied to the extent that it seeks an amendment to the language of the Memorandum Opinion or approval of any other specific arrangement.

Date: August 19, 2020

/s/ Theodore D. Chuang
THEODORE D. CHUANG
United States District Judge