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

MEMORANDUM OPINION

Plaintiffs American College of Obstetricians and Gynecologists ("ACOG"), Council of University Chairs of Obstetrics and Gynecology ("CUCOG"), New York State Academy of

Family Physicians ("NYSAFP"), SisterSong Women of Color Reproductive Justice Collective ("SisterSong"), and Honor MacNaughton, M.D. have filed a civil action against the United States Food and Drug Administration ("FDA"), FDA Commissioner Stephen M. Hahn, the United States Department of Health and Human Services ("HHS"), and Secretary of Health and Human Services Alex Azar ("the Secretary"), challenging the enforcement during the COVID-19 pandemic of certain FDA requirements relating to in-person dispensing and signature requirements for an oral medication used to induce an abortion or to manage a miscarriage. Plaintiffs have filed a Motion for a Preliminary Injunction seeking an order barring the enforcement of these requirements during the pandemic. The Motion is fully briefed, and the Court held a hearing on the Motion on June 19, 2020. For the reasons set forth below, Plaintiffs' Motion for a Preliminary Injunction is GRANTED IN PART and DENIED IN PART.

BACKGROUND

I. Medication Abortion

On September 28, 2000, FDA approved Mifeprex, the brand name for the drug mifepristone (collectively, "mifepristone"), as the first non-surgical abortion drug that, when taken in conjunction with another drug, misoprostol, can cause the early termination of an intrauterine pregnancy. In 2019, FDA approved a generic version of mifepristone. The use of mifepristone and misoprostol to cause an abortion, referred to as a medication abortion, is a two-part regimen ("the Mifepristone-Misoprostol Regimen"). First, the patient takes mifepristone, a single 200 mg tablet taken orally. Mifepristone blocks the body's receptors for the hormone necessary to sustain pregnancy, which then causes the pregnancy tissue and lining of the uterus to break down and separate from the uterine wall. Then, 24 to 48 hours after taking mifepristone, the patient takes misoprostol, another oral medication. Misoprostol causes uterine contractions that expel the

contents of the uterus. As a result, between 2 and 24 hours after taking misoprostol, the patient will experience cramping and bleeding that signals the pregnancy is being expelled.

The use of mifepristone in conjunction with misoprostol is also a widely accepted medical regimen to manage a miscarriage. While misoprostol alone has been prescribed after a miscarriage to completely expel the pregnancy, taking mifepristone first decreases the need for a follow-up, in-office procedure to fully evacuate the uterus.

II. FDA Regulation

When FDA first approved mifepristone in 2000, it recognized that the drug carried serious risks, such as an incomplete abortion or serious bleeding. In an effort to mitigate potential complications, FDA put in place several restrictions on dispensing and distributing the drug, including that the drug be prescribed only by a qualified physician and that it be administered in a hospital, clinic, or medical office only by or under the supervision of such a physician. In 2007, FDA deemed the imposed restrictions to be an approved Risk Evaluation and Mitigation Strategy ("REMS"), a statutorily authorized designation which allows for additional FDA restrictions beyond those set forth on the drug's labeling. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301-399i (2018), the federal government can enforce REMS against healthcare providers and the manufacturer of the drug, known as the "drug sponsor." *See, e.g.*, 21 U.S.C. § 355(p)(1)(B) (prohibiting a person from introducing or delivering a new drug into interstate commerce if the person fails to maintain compliance with the REMS); 21 U.S.C. § 333(f)(4)(A) (subjecting a drug manufacturer as a "responsible person" to civil penalties for violations of the REMS scheme).

In 2011, FDA approved the existing mifepristone REMS with additional Elements to Assure Safe Use ("ETASU"), a special category of REMS. An ETASU can be imposed on a drug

that has been "shown to be effective" but is "associated with a serious adverse drug experience" such that it can be approved only on the condition that the designated elements are satisfied. 21 U.S.C. § 355-1(f)(3). The ETASU requirements imposed in 2011 consisted of provisions mandating that the drug be prescribed only by specially certified physicians, that it be dispensed only in hospitals, clinics, or medical offices, and that it be dispensed only with documentation that certain safe-use conditions were met, such as securing the signature of the patient on a Patient Agreement Form and providing that form and a Medication Guide to the patient.

In 2013, FDA reviewed the existing REMS and reaffirmed the elements already in place. Three years later, in 2016, in response to a supplemental application by the drug sponsor requesting modifications to the REMS, 21 U.S.C. § 355-1(g)(4), FDA conducted another review of the existing mifepristone REMS. In that review, FDA determined that "no new safety concerns have arisen in recent years and that the known serious risks occur rarely," and that "[g]iven that the numbers of . . . adverse events appear to be stable or decreased over time, it is likely that . . . serious adverse events will remain acceptably low." 2016 Clinical Review at 39, 47, 49, Opp'n Mot. PI Ex. 19, ECF No. 62-11. As a result of the review, FDA made several changes to the REMS. Going forward, FDA permitted certain nonphysicians to prescribe the drug as long as they meet certain certification requirements, in part because the review "clearly demonstrate[d] that efficacy is the same with non-physician providers compared to physicians." *Id.* at 43. FDA also eliminated the requirement that the drug be administered in a hospital, clinic, or medical office and instead permitted it to be self-administered by the patient at a different location, based on the finding that there is "no significant difference in either efficacy or safety" for women who take both mifepristone and misoprostol at home as compared to women who take mifepristone at a medical office and misoprostol at home. *Id.* at 39. FDA also extended the gestational period during which

the medication is approved for use from seven weeks to ten weeks into a pregnancy. Of the requests made during this REMS review, the drug sponsor did not ask for changes to, or elimination of, the requirement that the drug be dispensed only in person at a healthcare facility.

Mifepristone is thus presently subject to three ETASU requirements. The first ETASU requirement, adopted pursuant to the "ETASU A" category which requires that "health care providers who prescribe the drug have particular training or experience or are specially certified," 21 U.S.C. § 355-1(f)(3)(A), provides that prescribing healthcare providers must certify in a written form submitted to the drug sponsor that they have certain required qualifications, such as the ability to assess the duration of the pregnancy and to diagnose an ectopic pregnancy, and will comply with specific use guidelines, including providing counseling about the risks of the Mifepristone-Misoprostol Regimen, providing and reviewing the Patient Agreement Form, as discussed below, and recording the serial number of each package of mifepristone in the patient's medical records.

The second ETASU requirement, imposed under the "ETASU C" category which "requires that the drug be dispensed to patients only in certain health care settings," 21 U.S.C. § 355-1(f)(3)(c), provides that mifepristone may be dispensed only in a hospital, clinic, or medical office, by or under the supervision of a certified healthcare provider ("the In-Person Dispensing Requirement"). Under this requirement, patients are not permitted to obtain mifepristone through a mail-order or retail pharmacy or to receive the medication by mail from their healthcare provider even if otherwise permitted by state law. Of the approximately 17 drugs subject to ETASU C, mifepristone is the only one for which the patient may take the medication alone, without clinical supervision.

The third ETASU requirement, adopted under the "ETASU D" category which provides that the drug "be dispensed to patients with evidence or other documentation of safe-use

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.