American College of Obstetricians & Gynecologists et al v. United States...rug Administration et al Doc. 144

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

On July 13, 2020, this Court granted a Motion for a Preliminary Injunction filed by Plaintiffs and thus enjoined Defendants, including the United States Food and Drug Administration

Dockets.Justia.com

("FDA"), the United States Department of Health and Human Services ("HHS"), and Secretary of Health and Human Services Alex Azar ("the Secretary"), from enforcing during the COVID-19 pandemic FDA requirements that mifepristone, an oral medication used as part of a regimen to induce an abortion, must be dispensed in person after the patient has signed a Patient Agreement Form. Prelim. Inj. at 2-3, ECF No. 92. Pending before the Court is Defendants' Renewed Motion to Stay the Preliminary Injunction and for an Indicative Ruling Dissolving the Preliminary Injunction, which is now fully briefed. Upon inquiry by the Court on October 15, 2020, the parties stated that they do not request a hearing on the Motion, and, in the absence of identified factual disputes, the Court finds that no hearing is necessary. See D. Md. Local R. 105.6. For the reasons set forth below, the Motion will be DENIED.

BACKGROUND

The claims in this case, and the findings of fact and conclusions of law on which the Court based the issuance of the July 13, 2020 preliminary injunction ("the Preliminary Injunction") are fully described in the Court's memorandum opinion of that date, which is incorporated herein by reference. *See Am. Coll. of Obstetricians & Gynecologists v. U.S. Food & Drug Admin.*, ___ F. Supp. 3d ___, No. TDC-20-cv-1320, 2020 WL 3960625, at *1-7 (D. Md. July 13, 2020) ("*ACOG*"). Additional background information and facts specific to the Motion are provided below.

I. Procedural History

On July 13, 2020, the Court issued the Preliminary Injunction enjoining Defendants from enforcing the FDA's in-person dispensing and signature requirements for mifepristone ("the In-Person Requirements") until 30 days after the end of the public health emergency ("PHE"), as declared by the Secretary pursuant to 42 U.S.C. § 247d(a), relating to the COVID-19 pandemic. On July 22, 2020, Defendants appealed the Preliminary Injunction to the United States Court of

Appeals for the Fourth Circuit. On July 24, 2020, Defendants filed with this Court a Motion to Stay the Preliminary Injunction pending the appeal, which was denied on July 30, 2020. Defendants then filed a Motion to Stay with the Fourth Circuit, which denied it on August 13, 2020.

On August 26, 2020, Defendants filed with the United States Supreme Court an Application for a Stay of the Preliminary Injunction pending appeal. Mot. Stay Prelim. Inj., *U.S. Food & Drug Admin. v. Am. Coll. of Obstetricians & Gynecologists*, No. 20A34 (U.S. Aug. 26, 2020). On October 8, 2020, the Supreme Court issued an order holding Defendants' application "in abeyance to permit the District Court to promptly consider a motion by the Government to dissolve, modify, or stay the injunction, including on the ground that relevant circumstances have changed." Order, *U.S. Food & Drug Admin. v. Am. Coll. of Obstetricians & Gynecologists*, No. 20A34 (U.S. Oct. 8, 2020). The Supreme Court further stated that "[t]he District Court should rule within 40 days of receiving the Government's submission." *Id.* On October 30, 2020, Defendants filed their Renewed Motion to Stay the Preliminary Injunction and for an Indicative Ruling Dissolving the Preliminary Injunction ("the Motion"), arguing that changed circumstances render Plaintiffs unlikely to succeed on the merits of their underlying claim, such that a stay or dissolution of the Preliminary Injunction is now warranted.

II. Additional Facts

With the Motion, Defendants have supplemented the record with declarations from state government officials of seven different states describing changes to public health restrictions and guidance in their states during the COVID-19 pandemic. Defendants also cite to publicly available media reports, scientific articles, and government websites and ask the Court to take judicial notice of additional facts "from sources whose accuracy cannot reasonably be questioned," including government websites. Renewed Mot. Stay ("Mot.") at 6, ECF No. 141-1 (quoting Fed. R. Evid.

201(b)(2)). Accordingly, and pursuant to the approach agreed to by the parties at the hearing on the original Motion for a Preliminary Injunction, the Court will take judicial notice of updated facts and circumstances from federal and state government websites relating to the state of the COVID-19 pandemic up to the date of the issuance of this opinion. *See* Fed. R. Evid. 201(b)(2); *United States v. Garcia*, 855 F.3d 615, 621 (4th Cir. 2017) ("This court and numerous others routinely take judicial notice of information contained on state and federal government websites."). In opposing the Motion, Plaintiffs also cite various media, scientific, and government sources and have submitted the declarations of five expert witnesses consisting of two epidemiologists, a physician and public health expert, a reproductive health physician, and an economist. The parties generally do not contest the facts and opinions offered by the other side.

A. The COVID-19 Pandemic

According to the Centers for Disease Control and Prevention ("CDC"), a component of HHS, as of July 2020, the United States had had over three million cases of COVID-19 resulting in over 130,000 deaths, with the number of new cases per day surpassing 44,000 each day in July leading up to the Court's issuance of the Preliminary Injunction on July 13, 2020. *See ACOG*, 2020 WL 3960625, at *4. As of December 5, 2020, the United States has had approximately 14.5 million total cases of COVID-19 and has sustained more than 280,000 deaths from the coronavirus. *Trends in Number of COVID-19 Cases and Deaths in the US Reported to CDC, by State/Territory*, U.S. Ctrs. for Disease Control & Prevention, https://covid.cdc.gov/covid-data-tracker/#trends_dailytrendscases (last visited Dec. 8, 2020) [hereinafter "CDC, *COVID-19 Data*"] (United States "Cases" and "Deaths" by "Total"). On that date, the nation had 206,992 new cases and had surpassed 100,000 cases for 28 straight days, with cases surpassing 150,000 20 times during that time period. *Id.* (United States "Cases" by "Daily Trends"). In the seven days leading

up to December 5, over 1.3 million new cases were reported, for a seven-day moving average of 188,504 new cases per day. *Id.*

As of November 12, 2020, the daily number of new cases was increasing in 46 states. Reingold Decl. ¶ 8, Opp'n Mot. Ex. 1, ECF No. 142-1. In 49 states and the District of Columbia, the seven-day moving average number of new COVID-19 cases is higher now than when the Preliminary Injunction was issued in July 2020. *See* CDC, *COVID-19 Data* ("Cases" by "Daily Trends" for each state).

The current data thus shows that infection rates are increasing dramatically as compared to July 2020. According to Dr. Arthur Reingold, Division Head of Epidemiology at the University of California at Berkeley School of Public Health, because the rates of hospitalizations and positive tests are also increasing, the higher cases numbers reflect a true rise in the incidence of COVID-19 nationwide. Reingold Decl. ¶¶ 9-10. Dr. Reingold has concluded that the severity of the pandemic will likely intensify in the coming months, both because the risk of infection will only increase as Americans travel for the holidays and gather indoors during the winter, and because of recent studies that have shown that the coronavirus can become aerosolized and therefore spread more easily. *Id.* ¶¶ 15, 28. Consistent with this opinion, on November 2, 2020, Dr. Deborah Birx, Coordinator of the White House Coronavirus Task Force, issued a report stating that the nation is "entering the most concerning and most deadly phase of this pandemic." *Id.* ¶ 18.

According to Dr. Mary Travis Bassett, Director of the François-Xavier Bagnoud Center for Health and Human Rights at Harvard University, this ongoing resurgence of COVID-19 presents a particularly significant risk to abortion patients because more than half of all abortion patients identify as Black or Hispanic, and at least 75 percent are low-income, while the death rate from COVID-19 is approximately three times higher among Black and Hispanic individuals as

compared to non-Hispanic white individuals, and younger Blacks and Hispanics ages 25 to 44 are 700 percent to 900 percent more likely to die from the coronavirus than whites of the same age. Bassett Decl. ¶¶ 15-16, 19, 21, Opp'n Mot. Ex. 2, ECF No. 142-2. According to a recent study, pregnant women of these demographic groups represent a disproportionately higher percentage of pregnant women who die from COVID-19. *Id.* ¶ 22.

Even with the current progress on vaccines and medical treatments, even a vaccine approved imminently will likely not be widely administered until spring 2021, and even then, 40 to 50 percent of the population may decline to get vaccinated. Reingold Decl. ¶¶ 19-21, 23. As Dr. Reingold has noted, recently considered or approved medical treatments such as remdesivir are not yet widely available, do not cure COVID-19 or make transmission of the virus harder, and instead are primarily used to treat high-risk or already severely ill patients. *Id.* ¶¶ 35-36.

B. HHS and FDA Actions

At the time of the issuance of the Preliminary Injunction, the Secretary had previously declared the nationwide PHE relating to the COVID-19 pandemic, and HHS and FDA had taken actions to temporarily allow the prescription of certain opioids without an in-person evaluation, and to temporarily decline to enforce requirements for administering certain drugs at a medical facility and for conducting in-person laboratory testing and imaging studies before prescribing certain other drugs. *ACOG*, 2020 WL 3960625, at *19. On October 2, 2020, based on the "continued consequences" of the COVID-19 pandemic, the Secretary renewed the PHE, for a third time, on a nationwide basis. *Renewal of Determination that a Public Health Emergency Exists*, Health & Human Servs. (Oct. 2, 2020), https://www.phe.gov/emergency/news/healthactions/phe/Pages/covid19-2Oct2020.aspx [hereinafter "HHS, *Third PHE Declaration*"]. All of the HHS and FDA actions relating to in-person evaluations and procedures remain in effect,

on a nationwide basis. Sarpatwari Decl. ¶ 12, Opp'n Mot. Ex. 4, ECF No. 142-4. Another such action, FDA guidance issued in March 2020 to allow drug sponsors to temporarily forgo certain in-person actions during clinical trials, was renewed in September 2020 without changes to the relevant provisions. *Id.* ¶ 22. According to Dr. Ameet Sarpatwari, an epidemiologist and an Assistant Professor at both Harvard Medical School and the Harvard T.H. Chan School of Public Health, because the ongoing and updated guidance from HHS and FDA to effectively suspend in-person requirements relates to matters with more significant health risks than those caused by the dispensing of mifepristone without fulfilling the In-Person Requirements, the fact that such guidance remains in effect is inconsistent with the position that COVID-19 health risks are now so minimal that the Preliminary Injunction should be lifted. *Id.* ¶¶ 9, 24.

C. State Experiences

Defendants have presented declarations from state government officials of seven states: Alabama, Idaho, Indiana, Kentucky, Mississippi, Nebraska, and Oklahoma. In general, the declarations primarily describe the imposition in each state in March or April 2020 of closures or public health restrictions relating to some combination of businesses, restaurants and bars, public facilities, social gatherings, medical procedures, schools, and childcare facilities; the subsequent relaxation of some or all of those restrictions over time; and, in some instances, the imposition of mandates to wear face masks. In Alabama, for example, the state began to re-open in stages starting in April and continuing into May, and many schools opened in the fall. Harris Decl. ¶¶ 13-17, 22, Mot. Ex. 1, ECF No. 141-4. Although many of the state's childcare facilities closed in March 2020 for economic reasons, through a grant program, Alabama facilitated the opening of 76 percent of childcare centers by early September 2020. Buckner Decl. ¶¶ 3-4, 7, Mot. Ex. 8, ECF No. 141-11. After a mask requirement was imposed in July 2020, the 14-day moving average

of new COVID-19 cases dropped from 1,753 per day to 704 by October 20, 2020, and the number of COVID-19 hospitalizations dropped from 1,335 to 859 by October 19, 2020. Harris Decl. ¶¶ 18, 20-21.

In Mississippi, after the adoption of a shelter-in-place order on April 1, 2020 and a ban on non-essential elective surgeries for the month of April, restrictions were gradually eased beginning in mid-April, public schools opened in the fall, and by September 30, 2020, the remaining COVID-related restrictions had been eased or lifted, though there remain limitations on the operational capacity of certain businesses. Dobbs Decl. ¶¶ 6-13, Mot. Ex. 5, ECF No. 141-8. At that time, a mandatory mask mandate was eased to require masks only under limited circumstances. *Id.* ¶ 12. Oklahoma lifted initial restrictions on businesses and elective medical procedures beginning in late April 2020, and by June 1 it had entered the last phase of reopening without restriction. Budd Decl. ¶¶ 7-9, Mot. Ex. 6, ECF No. 141-9. Schools, which closed in March, "largely re-opened" in the fall with in-person learning in most but not all districts. *Id.* ¶ 11. Childcare centers were never ordered closed and have received emergency funding. *Id.* ¶ 14.

Kentucky lifted closures of businesses, childcare centers, and other facilities in May and early June 2020, subject to continuing capacity and social distancing guidance. Fawns Decl. ¶¶ 13-22, Mot. Ex. 2, ECF No. 141-5. The state imposed a mask mandate in July 2020 and was able to reopen most schools in the fall. *Id.* ¶¶ 25-26. In Indiana, initial restrictions were lifted through a phased reopening beginning on May 4, 2020, and as of September 26, 2020, capacity restrictions were removed for social gatherings, restaurants and bars, and other venues. Foster Decl. ¶¶ 9-14, Mot. Ex. 4, ECF No. 141-7. Indiana continues to require individuals to wear masks. *Id.* ¶ 14.

In Nebraska, by July 6, 2020, earlier restrictions on restaurants and bars, public gatherings, and childcare centers had been eased, and restrictions on elective medical procedures had been

eliminated. Anthone Decl. ¶¶ 5-12, Mot. Ex. 3, ECF No. 141-6. By September 21, 2020, the remaining restrictions were largely ended. *Id.* ¶¶ 7-12. The state permitted schools to reopen for in-person classes in the fall, and many school districts, but not all, have done so. *Id.* ¶¶ 10, 12. As for Idaho, on June 13, 2020, the state entered the fourth stage of reopening, which generally allowed businesses to operate and gatherings to occur, subject to social distancing and sanitation requirements. Kane Decl. ¶ 7, Mot. Ex. 7, ECF No. 141-10 (citing *Stage 4 Stay Healthy Guidelines*, Idaho Rebounds: Our Path to Prosperity (June 13, 2020), https://rebound.idaho.gov/stage-4-stay-healthy-guidelines/). As of October 22, 2020, approximately 75 percent of schools were fully open with in-person learning, with most of the rest having some in-person and some online learning. *Id.* ¶ 11.

Both Indiana and Nebraska report that although their state laws require in-person examinations before any abortion, including a medication abortion, the number of abortions in these states in 2020 have exceeded the number that occurred in 2019. Foster Decl. ¶¶ 17-18; Anthone Decl. ¶ 14.

Notably, as of December 5, 2020, the most recent date for which the CDC has reported seven-day moving averages for all of these states,[1] all seven states have now experienced significant growth in average daily new cases as compared to when the Preliminary Injunction was issued on July 13, 2020, and all but one have seen such growth in the average daily deaths from COVID-19, with particularly significant increases in most of those numbers since the filing of the

[1] Although gaps in reported daily data have prevented the CDC from providing seven-day moving averages for Oklahoma for later dates, Oklahoma's COVID-19 case dashboard reports a seven-day moving average for December 6, 2020 of 2,270 daily new cases. *See COVID-19 Cases - Main Page*, Oklahoma State Dep't of Health, https://oklahoma.gov/covid19.html (last visited Dec. 8, 2020) (Oklahoma "Case Status by Date of Onset" displayed by "Trend Line").

Motion on October 30, 2020 and the completion of the briefing on November 20, 2020, as set forth below:

Seven-Day Moving Average of New Daily COVID-19 Cases					
	7/13/20	10/30/20	11/20/20	12/5/20	% Change (7/13 to 12/5)
United States	60,491	79,603	164,850	188,504	212%
Alabama	1,525	1,368	2,108	3,228	112%
Idaho	478	876	1,423	1,435	200%
Indiana	529	2,597	6,535	6,573	1,143%
Kentucky	357	1,642	2,766	3,411	855%
Mississippi	897	724	1,294	1,878	109%
Nebraska	193	1,019	2,391	1,892	880%
Oklahoma	619	907	2,436	2,837	358%

See CDC, *COVID-19 Data* ("Cases" by "Daily Trends" for each listed state) [hereinafter "Average Cases Table"]; *see also* Reingold Decl. ¶ 41.

Seven-Day Moving Average of New Daily COVID-19 Deaths					
	7/13/20	10/30/20	11/20/20	12/6/20	% Change (7/13 to 12/6)
United States	726	816	1,434	2,138	194%
Alabama	16	10	31	43	169%
Idaho	1	9	13	17	1,600%
Indiana	9	27	49	77	756%
Kentucky	5	11	16	25	400%
Mississippi	22	11	16	22	0%
Nebraska	1	7	17	29	2,800%
Oklahoma	3	10	11	14	367%

See CDC, *COVID-19 Data* ("Deaths" by "Daily Trends" for each listed state) [hereinafter "Average Deaths Table"].

According to Dr. Bassett, the significant increase in COVID-19 cases across the nation is partially driven by the reopening practices of these and other states. Bassett Decl. ¶ 16.

As a result of the resurgence of COVID-19, since late October and into November 2020, all of these states have started to reinstitute more stringent public health restrictions. For example, in Nebraska, as of October 21, 2020, more stringent limitations were issued for restaurants and

social gatherings, and elective surgeries were restricted at medical facilities that cannot maintain a certain level of resources for COVID-19 care. Anthone Decl. ¶¶ 5-9. In Kentucky, on November 18, 2020, restrictions were reimposed on restaurants, bars, offices, indoor recreation facilities, theaters and event spaces, social gatherings, and schools, including suspending in-person school instruction for all public and private schools, with the closure for middle and high schools extending until January 2021. *Gov. Beshear Implements New Restrictions to Save Lives*, Office of the Governor (Nov. 18, 2020), https://kentucky.gov/Pages/Activity-stream.aspx?n=GovernorBeshear&prId=475 [hereinafter "Office of the Governor, *Kentucky Nov. 18 Restrictions*"]. In Alabama, beginning on November 8, 2020, the state imposed stricter social distancing requirements on retailers, close-contact service providers, athletic facilities, entertainment venues, and restaurants. *Order of the State Health Officer Suspending Certain Public Gatherings Due to Risk of Infection by COVID-19*, Alabama State Health Officer 5-7, 11 (amended Nov. 5, 2020) https://www.alabamapublichealth.gov/legal/assets/order-adph-cov-gatherings-110520.pdf.

D. The Economic Impact

Although unemployment rates have declined since peaking in April 2020, according to Trevon Logan, Professor of Economics and Interim Dean of Social and Behavioral Sciences at the Ohio State University, the current state of the economy remains "quite poor." Logan Decl. ¶¶ 9, 12, Opp'n Mot. Ex. 5, ECF No. 142-5. Unemployment rates remain double what they were in February 2020, and even as of October 31, 2020, the number of individuals filing new unemployment claims remained higher than at any point in history before the COVID-19 pandemic. *Id.* ¶¶ 12-13. In October 2020, the numbers of long-term unemployed individuals and discouraged workers who have given up looking for employment both grew by over 1.2 million

and 1.7 million, respectively. *Id.* ¶¶ 14, 16. Recent U.S. Census Bureau surveys establish that as of October 2020, approximately 25 percent of adults in the United States expect a loss of income in their household in the next month, more than 30 percent have difficulty paying ordinary household expenses, and almost 10 percent do not have enough to eat. *Id.* ¶¶ 19, 21. At the same time, the economic and relief programs from the CARES Act have expired and have not been renewed. *Id.* ¶¶ 18, 22. These economic difficulties disproportionately affect low-income women of color who comprise the majority of abortion patients, as the unemployment rate among Blacks remains over 10 percent, and 80 percent of all exits from the labor force in September 2020 were by women. *Id.* ¶¶ 26-27. According to Professor Logan, the economic challenges faced by low-income communities, communities of color, and women with children will persist for the foreseeable future. *Id.* ¶ 29.

E. The Patient Experience

Beyond the ongoing and anticipated impact of COVID-19, Plaintiffs have provided a declaration from Plaintiff Dr. Honor MacNaughton, a board-certified physician practicing in primary care clinics in Massachusetts and an Associate Professor at Tufts University School of Medicine, who describes ongoing barriers to patients' ability to meet the In-Person Requirements. Dr. MacNaughton's clinics continue to operate at only 20 percent capacity, with the reproductive health clinics open only for half days, twice a week, and bringing children to the clinics is strongly discouraged. MacNaughton Decl. ¶¶ 6, 11, Opp'n Mot. Ex. 3, ECF No. 142-3. With COVID-19 cases on the rise, Dr. MacNaughton's patients continue to struggle with childcare challenges or other logistical difficulties of getting to a doctor's office. *Id.* ¶¶ 7, 9, 11. For example, one patient had several high-risk factors for COVID-19, had quit her job to avoid viral exposure, and had difficulty making an appointment due to the clinic's reduced hours. *Id.* ¶ 5. Another patient shares

a home with two elderly relatives and a young child, does not have a car, and thus would have to take public transportation or a ride share to go to the clinic. *Id.* ¶ 9. Another has three children attending school remotely and lacks childcare. *Id.* ¶ 8. Dr. MacNaughton further reported that because of the Preliminary Injunction, these patients were evaluated through telemedicine, received mifepristone through delivery, and took the dose, without logistical or medical complications. *Id.* ¶ 10.

DISCUSSION

In the Motion, Defendants argue that the Preliminary Injunction should be stayed or dissolved because of "changed circumstances" since the issuance of the Preliminary Injunction on July 13, 2020. Mot. at 1. Defendants also argue that, at a minimum, the Preliminary Injunction should be stayed in part or modified because the scope of the injunction is too broad in light of variations in the conditions in different states and across time.

I. Legal Standards

Under Federal Rule of Civil Procedure 62(d), while an interlocutory order granting a preliminary injunction is on appeal, a court may "suspend" the injunction. Fed. R. Civ. P. 62(d). In considering a motion to stay under this provision, the Court must consider (1) whether the stay applicant has made a "strong showing" of a likelihood of success on the merits; (2) "whether the applicant will be irreparably injured absent a stay"; (3) "whether issuance of the stay will substantially injure the other parties interested in the proceeding"; and (4) "where the public interest lies." *Hilton v. Braunskill*, 481 U.S. 770, 776 (1987); *see Long v. Robinson*, 432 F.2d 977, 979 (4th Cir. 1970).

Ordinarily, dissolution or modification of an existing preliminary injunction is "proper only when there has been a change of circumstances between the entry of the injunction and the filing

of the motion that would render the continuance of the injunction in its original form inequitable." *Favia v. Ind. Univ. of Penn.*, 7 F.3d 332, 337 (3d Cir. 1993); *see Gooch v. Life Investors Ins. Co. of Am.*, 672 F.3d 402, 414 (6th Cir. 2012); *see also Multi-Channel TV Cable Co. v. Charlottesville Quality Cable Operating Co.*, 60 F.3d 823, 1995 WL 406612, at *3 (4th Cir. 1995) (unpublished table decision). To obtain such a dissolution or modification, the moving party must demonstrate "significant changes in fact, law, or circumstance since the previous ruling." *Gooch*, 672 F.3d at 402 (quoting *Gill v. Monroe Cty. Dep't of Soc. Servs.*, 873 F.2d 647, 648–49 (2d Cir. 1989)); *see Favia*, 7 F.3d at 344 (referring to the moving party's "burden of demonstrating a 'significant' change in facts"); *Stone v. Trump*, 400 F. Supp. 3d 317, 332 (D. Md. 2019) (holding that a party moving to dissolve or modify a preliminary injunction must establish "a significant change either in factual conditions or in law" that makes "enforcement of the [preliminary injunction] . . . detrimental to the public interest"). "Minor changes in the facts or law usually are insufficient." *Multi-Channel TV Cable*, 1995 WL 406612, at *3.

While a preliminary injunction is on appeal, a district court ordinarily may not dissolve or modify it. *See, e.g., Doe v. Pub. Citizen*, 749 F.3d 246, 258 (4th Cir. 2014). Upon a motion seeking such action, however, a court may issue an indicative ruling stating "either that it would grant the motion if the court of appeals remands for that purpose or that the motion raises a substantial issue." Fed. R. Civ. P. 62.1(a). The moving party would then convey that ruling to the United States Court of Appeals to determine whether remand for such a decision is warranted. *See* Fed. R. Civ. P. 62.1(b), (c); Fed. R. App. P. 12.1.

II. Stay or Dissolution

A. Changed Circumstances

As to whether they can presently make a strong showing of a likelihood of success on the merits, Defendants argue only that changed circumstances establish that the In-Person Requirements no longer present an undue burden to women seeking a medication abortion during the COVID-19 pandemic. Specifically, Defendants argue that the Court's prior findings regarding the burdens facing abortion patients during the COVID-19 pandemic, such as the increased health risks associated with travel to medical facilities, the closure of or limited access to medical facilities, greater childcare and transportation challenges, and the economic impact of the pandemic on economically disadvantaged women and people of color have "either been mitigated or resolved." Mot. at 5. Based on the evidence presented, the Court finds no such changed circumstances because (1) the COVID-19 pandemic continues to pose a significant health risk necessitating the Preliminary Injunction; and (2) as a result of that ongoing risk, the specific barriers underlying the undue burden determination have not been sufficiently "mitigated or resolved" to alter the likelihood of success on the merits and to warrant a stay or dissolution. *Id.*

1. Health Risk

In finding that the In-Person Requirements currently pose an undue burden on women seeking a medication abortion, the Court focused primarily on the determination that "the COVID-19 pandemic has created a significant burden upon patients and the public that renders travel to medical facilities fraught with health risk to themselves, medical professionals, others they encounter during such trips, and the members of their households to whom they return." *ACOG*, 2020 WL 3960625, at *20. The evidence establishes that since the Court granted the Preliminary Injunction on July 13, 2020, this health risk has only gotten worse. Since that date, the number of

COVID-19 cases in the United States has increased four-fold, from over three million to more than 14.5 million, and the number of deaths from COVID-19 have more than doubled, from 130,000 to more than 280,000. *Id.* at *19; CDC, *COVID-19 Data.* As of July 13, 2020, the seven-day moving average of new cases per day nationwide was approximately 44,000; as of December 5, 2020, it was 188,504. *See ACOG*, 2020 WL 3960625, at *19; CDC, *COVID-19 Data.* According to Dr. Reingold, because the percentage of positive tests is also increasing, the dramatic rise in the number of COVID-19 cases relative to earlier time periods reveals a true rise in case numbers. Reingold Decl. ¶ 9. This increase is not limited to any one part of the nation. In 49 states and the District of Columbia, the seven-day moving average of daily new cases is higher now than in July 2020. CDC, *COVID-19 Data.*

The severity of the pandemic is expected to intensify in the coming months. As noted by Dr. Reingold and Dr. Bassett, with the colder weather keeping more people indoors in less ventilated spaces, and with the likelihood of more travel and indoor social gatherings during the holiday season, the rate of viral spread will likely increase, particularly in light of recent research supporting the conclusion that COVID-19 may be spread not only through droplet transmission, but also through airborne transmission of viral particles that can remain suspended in or travel in the air. Reingold Decl. ¶¶ 14-15 (citing *Coronavirus Disease 2019 (COVID-19), Scientific Brief: SARS-CoV-2 and Potential Airborne Transmission*, U.S. Ctrs. for Disease Control & Prevention, (Oct. 5, 2020), https://www.cdc.gov/coronavirus/2019-ncov/more/scientific-brief-sars-cov-2.html); Bassett Decl. ¶ 15. Notably, although the CDC, the National Institutes of Health ("NIH"), and the FDA are all components of HHS, Defendants have offered no expert opinions, from a scientist at one of these agencies or elsewhere in the federal government, to contradict the facts and conclusions provided by Dr. Reingold and Dr. Bassett. Rather, the current alarming trends

have led Dr. Anthony Fauci, Director of the National Institute of Allergy and Infectious Diseases at NIH, to state on October 30, 2020 that the United States is "in for a whole lot of hurt. It's not a good situation. . . . All the stars are aligned in the wrong place as you go into the fall and winter season, with people congregating at home indoors. You could not possibly be positioned more poorly." Reingold Decl. ¶ 18. As noted in the Court's prior memorandum opinion, where abortion patients in the United States are disproportionately low-income and women of color, the ongoing health risks from exposure to COVID-19 are even more pronounced. *ACOG*, 2020 WL 3960625, at *6. Not only is the death rate from COVID-19 3.6 times higher for Blacks than for non-Hispanic whites, but Black and Hispanic people ages 25 to 34 are more than 700 percent more likely to die from COVID-19 than white people in the same age range, and those between the ages of 35 and 44 are 900 percent more likely to die. Bassett Decl. ¶ 21.

Significantly, Defendants HHS and FDA have taken no specific actions that demonstrate that the health risks of the COVID-19 pandemic have abated in any way. Most notably, on October 2, 2020, the Secretary renewed, for the third time, the PHE. HHS, *Third PHE Declaration.* Further, since July 2020, HHS and FDA have not altered or rescinded their prior actions reflecting the health risks associated with in-person health care activities during the COVID-19 pandemic, as referenced in the Court's prior memorandum opinion, including HHS's prior invocation of the "telemedicine exception" to allow healthcare providers to forgo otherwise mandatory in-person evaluation of patients before prescribing certain controlled substances, including opioids which have recently led to a national health crisis of a different type, as well as the FDA's decisions that during the PHE it will not enforce certain requirements for the in-person administration of two specific drugs and for in-person laboratory testing and imaging before dispensing certain drugs, including drugs that can lead to lethal infections. *ACOG*, 2020 WL 3960625, at *4-5; Sarpatwari

Decl. ¶¶ 13-15, 18-19. Finally, in updated guidance issued in September 2020, the FDA maintained its March 2020 guidance that permitted modifications to FDA-approved clinical trial protocols to avoid in-person contact during the PHE. Sarpatwari Decl. ¶ 22. The fact that since July 2020, Defendants themselves have not altered or eliminated these specific actions taken to effectively provide exemptions from, or alternatives to, in-person requirements in light of the COVID-19 pandemic further supports the conclusion that the health risks associated with COVID-19 pandemic have not been reduced in any meaningful way.

In the face of the compelling data and evidence that, across the United States, the COVID-19 pandemic is substantially worse than in July 2020, Defendants argue that the health risk to women seeking a medication abortion is actually lower today based on certain specific developments, including the greater public health emphasis on the use of masks and the relaxation of public health restrictions imposed in the spring on the operation of certain businesses and institutions. Plaintiffs do not dispute that the CDC and certain state governments have increased their encouragement of wearing masks, and certain states, such as Alabama and Kentucky, have imposed mask requirements since July 2020. *See* Harris Decl. ¶ 18 (Alabama); Fawns Decl. ¶ 25 (Kentucky). But even in states with a mask mandate, whether because, as noted by Dr. Reingold and Dr. Bassett, citizens do not always comply with the mandates, or because masks offer only limited protection based on the quality of the material and of the fit and the risks presented by aerosol transmission of COVID-19, *see* Reingold Decl. ¶ 31, Bassett Decl. ¶ 33, the reality is that masks and mask mandates have not prevented the present spikes in COVID-19 cases across the country. For example, when Kentucky instituted a mask mandate on July 10, 2020, it had a seven-day moving average of 327 new cases per day, but as of October 30, that average was 1,642 new cases per day, and as of December 5, it was 3,411 cases per day. CDC, *COVID-19 Data* (Kentucky

"Cases" by "Daily Trends"); *see also* Reingold Decl. ¶ 41. Likewise, Indiana, which has had a mask mandate at least since September 2020, has seen its seven-day moving average of new cases grow from 529 cases per day on July 13, 2020, to 2,597 cases per day on October 30, and to 6,573 on December 5. *See* CDC, *COVID-19 Data* (Indiana "Cases" by "Daily Trends"); *see also* Reingold Decl. ¶ 41. Here in Maryland, although there has been a mask mandate in effect since July 31, 2020, the seven-day moving average of daily new cases has increased from 901 on that date to 2,654 on December 5, 2020, with the test positivity rate surpassing five percent on November 10, 2020 for the first time since June. *See* Governor of the State of Maryland, *Order No. 20-07-29-01* 9-10 (July 31, 2020), https://governor.maryland.gov/wp-content/uploads/2020/07/Gatherings-10th-AMENDED-7.29.20.pdf; CDC, *COVID-19 Data* (Maryland "Cases" by "Daily Trends"); *Governor Hogan Announces Series of Actions to Slow the Spread of COVID-19*, Governor's Office of Homeland Security (Nov. 10, 2020), https://gohs.maryland.gov/2020/11/10/governor-hogan-announces-series-of-actions-to-slow-the-spread-of-covid-19/. Where the present infection statistics at the end of 2020 greatly exceed those at or before the dates when mask mandates were issued, the use of masks and mask mandates plainly have not successfully decreased the overall health risk of the COVID-19 pandemic.

Likewise, Defendants' evidence that certain states relaxed public health restrictions since the spring of 2020 does not establish a decreased health risk. First, most of the reversals of closings and restrictions in the identified states occurred before the Preliminary Injunction was issued in July 2020. *See, e.g.*, Fawns Decl. ¶¶13-23 (describing Kentucky reopening actions up to June 15); Budd Decl. ¶¶ 8-9 (describing Oklahoma reopening actions ending in May 2020). In Alabama, for example, all of the identified steps to relax restrictions on in-person gatherings, business closings, and medical procedures were ordered by May 2020. Harris Decl. ¶¶ 13-17. Second,

whether because of the relaxed public health restrictions or not, the data now shows that conditions have greatly deteriorated in all of these states. For example, Nebraska's average daily new cases have increased from 193 on July 13, 2020, to 1,019 when the Motion was filed on October 30, 2020, to 1,892 as of December 5, 2020, with significant increases in daily deaths over the same time period. *See supra* Average Cases Table (Nebraska); Average Deaths Table (Nebraska); *see also* Reingold Decl. ¶ 41. Though Alabama reported improving conditions from July to October 2020, Harris Decl. ¶¶ 19-21, in the intervening weeks since Defendants filed the Motion, Alabama's average daily COVID-19 new cases and deaths have risen to the point that they are now more than double the comparable numbers from July 2020. *See supra* Average Cases Table (Alabama); Average Deaths Table (Alabama). Alabama's daily hospitalizations are also now markedly higher than in July 2020. *Alabama's COVID-19 Data and Surveillance Dashboard*, Alabama Dept. of Public Health, https://alpublichealth.maps.arcgis.com/apps/opsdashboard/index.html#/6d2771faa9da4a2786a509d82c8cf0f7 (last visited Dec. 7, 2020) (Dashboard No. 9). Notably, none of the other states provided data showing that the reopenings corresponded with reduced COVID-19 cases, and in fact all now have average daily new cases and deaths that are equal to, and in almost all cases substantially higher than, in July 2020. *See supra* Average Cases Table; Average Deaths Table.

Third, reflective of the present increased health risk, all of these states have now begun to reverse course and have, since October 2020, imposed or reimposed certain public health restrictions relating to the opening or operation of businesses and facilities. *See supra* Background Part II.C. (discussing Nebraska, Kentucky, and Alabama); *see also Stay Healthy Order,* State of Idaho, Idaho Department of Health and Welfare 1, 2 (Nov. 14, 2020), https://coronavirus.idaho.gov/wp-content/uploads/2020/11/stage-2-modified-order.pdf (noting

that reversion to an earlier stage of reopening was based in part on the fact that Idaho now has the second highest test positivity rate in the nation); State of Indiana, *County-Based Measures and Restrictions Based on the Impact and Spread of the Coronavirus Disease (COVID-19)* 3, 4, 7 (Nov. 13, 2020), https://www.in.gov/gov/files/Executive_Order_20-48_Color-Coded_County_Assessments.pdf.

For example, on November 16, 2020, the Governor of Oklahoma issued an emergency Executive Order, the provisions of which included imposing restrictions on the operation of restaurants and bars and an indoor mask requirement, as well as ordering that telemedicine "be used to maximum potential" and be allowed "for non-established patients" in response to COVID-19. *Seventh Amended Executive Order 2020-20*, Executive Department, Oklahoma Secretary of State ¶¶ 11, 24-26 (Nov. 16, 2020), https://www.sos.ok.gov/documents/executive/1971.pdf. Notably, the changes in Nebraska and Mississippi have included imposing certain restrictions on elective medical procedures. *See* Anthone Decl. ¶¶ 5, 7-9; *Executive Order No. 1527*, State of Mississippi, Office of the Governor (Oct. 19, 2020), https://www.sos.ms.gov/content/executive orders/ExecutiveOrders/1527.pdf; *Executive Order No. 1531,* State of Mississippi, Office of the Governor (Nov. 17, 2020), https://www.sos.ms.gov/content/executiveorders/ExecutiveOrders/1531.pdf. Likewise, in Maryland, as of November 11, 2020, the Governor increased restrictions on restaurants and indoor gatherings and returned state employees to mandatory teleworking. Governor of the State of Maryland, *Order No. 20-11-10-01* (Nov. 11, 2020), https://governor.maryland.gov/wp-content/uploads/2020/11/EO-11.10.20.pdf. Even this Court, after conducting some in-person court proceedings and trials beginning in August 2020, suspended all in-person court proceedings as of November 16, 2020. *See* Standing Order 2020-

20, *In Re: Court Operations Under the Exigent Circumstances Created by COVID-19*, No. 00-0308 (D. Md. Nov. 11, 2020).

Thus, the reopening of businesses and facilities for a certain period of time does not establish that the public health risk has decreased since July 2020. Rather, as acknowledged by Dr. Gary Anthone, Chief Medical Officer for Nebraska, it reflected judgments balancing economic needs, personal liberty, and other factors with public health risk. Anthone Decl. ¶ 3; *see also* Reingold Decl. ¶ 39. Indeed, the reopenings have likely contributed to the dramatic increases in cases at the present time. Bassett Decl. ¶ 16. Significantly, as noted by Dr. Reingold and Dr. Bassett, the fact that individuals are *permitted* to venture out during a pandemic to restaurants or businesses does not establish that women should be *mandated* to risk exposure to COVID-19 in order to exercise a constitutional right. Reingold Decl. ¶ 45; Bassett Decl. ¶¶ 41-42.

Finally, as to Defendants' claim that progress on medical treatments and vaccines for COVID-19 establishes changed circumstances sufficient to warrant a stay or dissolution of the Preliminary Injunction, the Court finds this argument premature. Although the FDA is now considering requests for Emergency Use Authorization ("EUA") for several vaccines, even if they are approved, the widespread distribution of vaccines likely will not occur until spring 2021, because of the significant task of manufacturing, distributing, and administering the vaccines, some of which require multiple doses several weeks apart. *See* Reingold Decl. ¶¶ 19-22. Recent reports also raise concerns that a significant portion of the population, as high as 50 percent, may decline to be vaccinated based on concerns about the approval process or other reasons for a lack of confidence. *Id.* ¶ 23. As for medical treatments for COVID-19, Defendants note that the FDA has now granted its first approval of a COVID-19 treatment called remdesivir, and it has issued EUAs for an antibody therapy known as bamlanivimab and for an at-home self-testing kit. As

noted by Dr. Reingold, however, remdesivir is not a cure for COVID-19 and does not prevent severe illness; rather, it is intended for use with patients who are already so ill as to require hospitalization to increase their odds of clinical improvement and survival. *Id.* ¶ 35. Bamlanivimab is presently authorized only for use by individuals with preexisting high-risk medical conditions to reduce the likelihood of severe symptoms. *Id.* ¶ 36. Both drugs, as well as the self-testing kit referenced by Defendants, are not yet widely available. *Id.* ¶¶ 35-36. Finally, the fact that as of November 28, 2020, the weekly hospitalization rate was at its highest point since the beginning of the pandemic, and COVID-19 deaths continue to rise across the nation, confirms that these medications are not yet reducing the health risk of COVID-19 in any significant way. CDC, *COVID-19 Data* (United States "Deaths" by "Daily Trends"); *COVIDView Weekly Summary: Key Updates for Week 48, Ending November 28, 2020*, U.S. Ctrs. For Disease Control & Prevention (Dec. 3, 2020), https://www.cdc.gov/coronavirus/2019-ncov/covid-data/pdf/covidview-12-04-2020.pdf. Likewise, the same data on hospitalizations and deaths belies Defendants' more general claim that greater medical understanding has led to "[i]ncremental improvements" in clinical outcomes that constitute changed circumstances. Reply Mot. at 5, ECF No. 143.

Accordingly, while the progress on vaccines and medical treatments for COVID-19 are cause for optimism and may advance the day that the Preliminary Injunction will no longer be warranted, the impact of these advances to date has not meaningfully altered the current health risks and obstacles to women seeking medication abortions. The Court therefore finds that these factors do not materially alter the likelihood of success on the merits or warrant a stay or dissolution of the injunction at the present time.

2. Specific Obstacles

Despite the clear evidence that the COVID-19 pandemic currently presents an even greater health risk than in July 2020, Defendants further argue that conditions have improved as to some of the specific challenges referenced by the Court as collectively establishing that the In-Person Requirements present an undue burden to women seeking a medication abortion. In particular, they argue that economic conditions and access to medical facilities, childcare, and transportation have improved sufficiently since the issuance of the Preliminary Injunction to warrant a stay or dissolution of the injunction.

First, Defendants assert that economic conditions have improved significantly so as to alter the analysis of undue burden. This claim is unpersuasive. Although Defendants note that the unemployment rate has declined since April 2020, both nationally and in certain states such as Kentucky, Fawns Decl. ¶ 28, as noted by Professor Logan, the economy remains "quite poor" by numerous measures, particularly for women with children in low-income communities and communities of color. Logan Decl. ¶ 9. The unemployment rate in October 2020 was still twice as high as it was in February 2020, and in the last week of October, more than 750,000 people filed new unemployment claims as compared to before the pandemic, a figure still higher than for any week in history prior to the onset of the pandemic. *Id.* ¶¶ 12-13. In October 2020, the number of long-term unemployed individuals was over 3.5 million, a 280 percent increase as compared to October 2019; 25 percent of Americans expected to lose employment income in their household in the next month; more than 30 percent of adults across the country reported difficulty paying for food, housing, and other ordinary household expenses; and 10 percent reported that they did not have enough to eat. *Id.* ¶¶ 19, 21. As particularly relevant to the demographic groups comprising the majority of women seeking a medication abortion, the Black unemployment rate remains over

10 percent, and 80 percent of all exits from the labor force in September 2020 consisted of women. *Id.* ¶¶ 26-27.

Second, Defendants argue that the ability to travel to a doctor's office has improved because more medical offices are open, childcare challenges are reduced because more schools and childcare centers are open, and public transportation is safer and more available. As to medical offices, where Defendants' declarations establish that early restrictions on medical offices or elective procedures in Kentucky and Mississippi were lifted by May 2020, those restrictions were not in place at the time that the Preliminary Injunction was issued in July 2020. Fawns Decl. ¶ 15 (Kentucky); Dobbs Decl. ¶ 7 (Mississippi). More significantly, as noted above, states such as Mississippi and Nebraska have recently imposed new public health limitations relating to medical facilities, requiring that certain hospital capacity be reserved for COVID-19 treatment as a condition of conducting elective medical procedures and surgeries. *See supra* Discussion Part II.A.1. Further, according to Dr. MacNaughton, outpatient health clinics such as her own are still operating at severely reduced capacity for public health reasons and thus have very limited appointment availability. MacNaughton Decl. ¶ 11. The Court therefore finds that Defendants have not shown that, especially going into December 2020, such facilities are now operating at capacities significantly higher than in July 2020.

Defendants also claim that the reopening of schools and childcare facilities has reduced the obstacles to women seeking a medication abortion because it alleviates the challenge of securing childcare during a visit to a medical office. Although Defendants assert that in Mississippi all schools opened for in-person learning, they have not made the same claim about the other six identified states. Dobbs Decl. ¶ 9 (Mississippi). Rather, they have acknowledged that though many schools in the other states opened completely, some percentage of the schools used a mix of

in-person and online learning or used online learning only. *See, e.g.*, Budd Decl. ¶ 11 (Oklahoma); Anthone Decl. ¶ 10 (Nebraska); Kane Decl. ¶ 4 (Idaho). More broadly, many school districts across the United States either did not resume in-person classes or did so only as part of a hybrid model in which both in-person classes and online classes were used. Logan Decl. ¶ 33. With the resurgence of COVID-19 cases this fall, numerous large school districts, such as those in New York City, Philadelphia, Boston, Chicago, and Columbus, Ohio, as well as in Maryland, have either had to postpone plans to reopen for in-person classes or to reverse course and suspend in-person classes in favor of remote learning. *Id.* Notably, since Defendants' declarations were submitted, Kentucky has actually ordered a suspension of in-person instruction at all public and private schools starting on November 23, 2020 for a minimum of two weeks at elementary schools and until January 2021 at middle and high schools. Office of the Governor, *Kentucky Nov. 18 Restrictions*. With such volatility in school schedules, childcare remains a significant challenge, particularly for low-wage workers. Logan Decl. ¶ 33.

As for childcare centers, where Oklahoma and Mississippi childcare centers did not close and Kentucky childcare centers reopened starting in mid-June 2020, Defendants have not identified a state that ordered the reopening of closed childcare centers after the issuance of the Preliminary Injunction. Budd Decl. ¶ 14; Dobbs. Decl. ¶ 9; Fawns Decl. ¶ 22. Even if, as in Nebraska and Alabama, some childcare center capacity increased after that date based on relaxation of capacity limits or state financial assistance, Anthone Decl. ¶ 12; Buckner Decl. ¶ 7, as noted by Professor Logan, access to childcare centers remains uncertain because they may be generally unavailable to women for financial reasons such as job loss, or specifically unavailable by policy at any time that any household member has been exposed to COVID-19, both more likely concerns for the majority of abortion patients who are low-income, women of color, or both.

Logan Decl. ¶¶ 11, 35. Finally, while Defendants have provided a specific example of a state that kept public transportation open despite pandemic prohibitions on mass gatherings, Fawns Decl. ¶ 6, and argue that many public transportation systems have instituted policies to improve safety, according to Dr. Reingold, taking public transportation still presents significant risks of infection, as a single infected passenger can transmit the disease, particularly in light of the recently discovered potential for aerosol transmission. Reingold Decl. ¶ 31.

For these reasons, and particularly in light of the substantial spread of COVID-19 in recent weeks that increases the risk of all travel, the Court does not find that any changes to economic conditions or access to medical facilities, childcare, or transportation since the issuance of the Preliminary Injunction have been so favorable as to constitute changed circumstances altering the likelihood of success on the merits and warranting a stay or dissolution of the injunction.

3. Additional "Changed Circumstances"

Defendants advance two remaining arguments. First, they offer the fact that in Indiana and Nebraska, where state law requires an in-person examination before any medication abortion, the number of abortions in 2020 have equaled or exceeded the number for comparable periods in 2019 and argue that the willingness of those patients to go to medical facilities for that procedure during the COVID-19 pandemic illustrates that the pandemic does not present an undue burden to fulfilling the In-Person Requirements and receiving a medication abortion. Foster Decl. ¶¶ 16-18; Anthone Decl. ¶¶ 13-14. Although this data may support Defendants' argument, it is too incomplete to allow for definitive conclusions. First, this data provides only limited information because it comes from only two states, both of which are states in which the Preliminary Injunction has no practical effect in light of state laws, includes data on procedural abortions unrelated to the Preliminary Injunction, and does not provide information on what obstacles and burdens were

encountered and overcome by these patients. Second, the data does not account for whether, as asserted in the expert opinion of Dr. Allison Bryant Mantha offered on the Motion for a Preliminary Injunction, the demand for abortions has increased during the COVID-19 pandemic because the same challenges to fulfilling the In-Person Requirements have made it more difficult and costly for women to obtain contraception, and unemployment and other pandemic-related challenges may cause some to conclude that they cannot support a new baby at this time. *See ACOG*, 2020 WL 3960625, at *7. Third, the data is countered by the accounts of Dr. MacNaughton describing multiple examples of actual patients, who, either because of specific risk of infection to themselves or elderly relatives or substantial childcare limitations, have continued to face significant barriers to fulfilling the In-Person Requirements yet were able to obtain a medication abortion without an office visit as a result of the Preliminary Injunction. MacNaughton Decl. ¶¶ 5-9. Thus, when considered alongside all of the other evidence in the record, the limited data from these two states does not provide a basis to stay or dissolve the injunction.

Second, Defendants ask the Court to reconsider the denial of a stay out of "deference" to the determinations of the FDA and cite the Supreme Court's recent refusal to enjoin a state's pandemic order in *South Bay United Pentecostal Church v. Newsom*, 140 S. Ct. 1613, 1614 (2020). Beyond this Court's prior analysis of the issue of deference as applied to the present case, *ACOG*, 2020 WL 3960625, at *24-25, the Court notes that no HHS or FDA public health official has actually offered an expert opinion that there are changed circumstances that warrant a stay or dissolution of the Preliminary Injunction. Moreover, the Supreme Court recently recognized the limits of deference when it stated that although judges "are not public health experts" and "should respect the judgment of those with special expertise," "even in a pandemic, the Constitution cannot be put away and forgotten." *Roman Catholic Diocese of Brooklyn v. Cuomo*, ___ S. Ct. ___, No.

20A87, 2020 WL 6948354, at *3 (U.S. Nov. 25, 2020). Where the Preliminary Injunction is aimed at upholding a constitutional right under the circumstances of a public health emergency, general deference to an FDA determination made seven years ago is not a sufficient basis to warrant its stay or dissolution. *See ACOG*, 2020 WL 3960625, at *24 (finding that the relevant decision was made in 2013).

B. Remaining Factors

For the reasons discussed above, the Court finds that there are insufficient changed circumstances since July 2020 to revisit the Court's assessment of the likelihood of success on the merits. *Hilton*, 481 U.S. at 776; *see also Favia*, 7 F.3d at 337. As to the other *Hilton* factors, Defendants offer no persuasive basis for the Court to revisit its prior determination that no stay is warranted upon consideration of whether there was irreparable injury to Defendants, whether there would be substantial injury to Plaintiffs upon issuance of a stay, and whether the public interest favors a stay. *See* Order at 2, ECF No. 110; *see also ACOG*, 2020 WL 3960625, at *31-32. In particular, with their Motion, Defendants have offered no evidence that their temporary inability to enforce the In-Person Requirements has injured them or, for that matter, harmed a patient. In fact, Dr. MacNaughton, the only expert who has provided evidence on the effect of the Preliminary Injunction on patients, has identified several examples of successful dispensing of mifepristone without any evidence of harm or danger to those patients arising from the lack of an in-person visit. MacNaughton Decl. ¶¶ 5-10. Dr. MacNaughton's account also illustrates that there may well be substantial injury to Plaintiffs' members and their patients if the Preliminary Injunction is stayed. Finally, the Court finds that particularly in light of the current acute impact of COVID-19 across the nation, the public interest weighs against a stay or dissolution of the Preliminary

Injunction, which at present has the positive effect of decreasing public travel during a pandemic. The Motion will therefore be denied as to both a general stay and dissolution.

III. Scope of the Injunction

Beyond seeking a broad stay or dissolution of the Preliminary Injunction, Defendants also seek a stay or modification of the scope of the injunction because "infection rates and trendlines are not uniform nationwide" and certain "[s]tates have shown success in managing and ultimately reducing spikes," Mot. at 23, and because a recent decision by the United States Court of Appeals for the Fourth Circuit disfavors nationwide injunctions adopted for pragmatic reasons. *See CASA de Maryland, Inc. v. Trump*, 971 F.3d 220, 262 (4th Cir. 2020).

As discussed above, even if at some point since the issuance of the Preliminary Injunction there have been signs that certain states were having success in responding to the COVID-19 pandemic, the current circumstances are uniformly dire across the nation. *See supra* Discussion Part II.A.1. Thus, at the present time, there is no meaningful basis by which to distinguish one state or region from others as uniquely free from the health risks, and thus the undue burden, imposed by the COVID-19 pandemic.

Defendants have effectively acknowledged this fact through their decisions and actions relating to the COVID-19 pandemic, which, from all angles, have been homogenous across all regions of the country. The Secretary's declaration of a public health emergency, first issued on January 31, 2020 and then renewed three times, has always maintained the scope of the declaration at a nationwide level. *See* HHS, *Third PHE Declaration*. The PHE declaration was framed in this way even though HHS has, in the recent past, issued geographically-limited PHE declarations under the same authority, such as an August 26, 2020 PHE for Louisiana and Texas due to hurricanes; August 26, 2020 and September 16, 2020 PHEs for California and Oregon,

respectively, due to wildfires; and an August 12, 2016 PHE for only Puerto Rico due to the Zika virus. *See Public Health Emergency Declarations*, Health & Human Servs., https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx (last visited Dec. 6, 2020).

Likewise, as discussed above, HHS and FDA, in response to the COVID-19 pandemic, acted to allow healthcare providers or drug sponsors to temporarily forgo certain in-person requirements. *See supra* Discussion Part II.A.1. All of these actions have been taken on a nationwide basis, with no variations in guidance for different regions or states, and none have been geographically limited since the issuance of the Preliminary Injunction. In fact, the guidance relating to clinical trials was updated in September 2020 without changes to the provisions permitting consideration of ways to avoid certain in-person contacts, and without any change to their nationwide scope. Sarpatwari Decl. ¶ 22; *compare* U.S. Food & Drug Admin., *FDA Guidance on Conduct of Clinical Trials of Medical Products During the COVID-19 Public Health Emergency* 6-7, 13-14 (updated Mar. 27, 2020), https://ictr.johnshopkins.edu/wp-content/uploads/FDA-ClinicalTrials-3-27-20.pdf *with* U.S. Food & Drug Admin., *FDA Guidance on Conduct of Clinical Trials of Medical Products During the COVID-19 Public Health Emergency* 6-7, 14-15 (updated Sept. 21, 2020), https://www.fda.gov/media/136238/download. Where Defendants themselves have not carved out certain states or regions from the HHS and FDA response to COVID-19 based on allegedly more favorable conditions in those areas, they effectively recognize that during the COVID-19 pandemic, conditions across the nation are sufficiently similar that there is no basis to draw the kinds of distinctions that Defendants propose here. Based on this fact, combined with the current evidence of consistently serious conditions

across the United States, the Court reaches this same conclusion and will not limit the Preliminary Injunction's applicability by geographic region.

As for Defendants' citation of *CASA de Maryland*, decided on August 5, 2020 and thus after the issuance of the Preliminary Injunction, Defendants focus on the statement in that case that "the district court improperly stepped into the shoes of [a federal agency] and displaced our democratic system of governance when it insisted that a nationwide injunction was necessary for pragmatic reasons." 971 F.3d at 262. In *CASA de Maryland*, the district court issued a nationwide injunction against the enforcement of an updated definition of a "public charge" under the Immigration and Nationality Act in part because "uniformity is important to immigration law," and because the members of the organization might travel and then enter the United States through ports of entry in a different part of the country and not receive the benefit of the injunction there. *CASA de Maryland, Inc. v. Trump*, 414 F. Supp. 3d 760, 769, 788 (D. Md. 2019). Defendants argue that the Fourth Circuit's statement undermines the Court's consideration, as one factor in the analysis, of the infeasibility of adopting a narrower injunction that accounts for "unpredictable changes" and "nuanced regional differences" in COVID-19 conditions across the nation. Mot. at 23.

As an initial matter, on December 3, 2020, the Fourth Circuit granted a petition for rehearing en banc in *CASA de Maryland*, so it is unclear whether the panel opinion or the language at issue will stand. *CASA de Maryland, Inc. v. Trump*, No. 19-222 (4th Cir. Dec. 3, 2020) (granting rehearing en banc). Even assuming that the ruling remains intact, Defendants' argument is unpersuasive for several reasons. First, as discussed above, at the present time, the conditions across the United States are universally critical, such that there is no basis to exclude certain states or regions based on favorable conditions in those locations. *See supra* Discussion Parts II.A.1, III.

Second, the Fourth Circuit's rejection of the nationwide injunction in *CASA de Maryland* was based primarily on its conclusion that the rationale that "uniformity is important to immigration law and anything other than a nationwide injunction would be impractical" is "unpersuasive" and "lacks any limiting principle," rather than on any new rule barring district courts from considering practical concerns in the administration of an injunction. 971 F.3d at 262. Notably, although the court criticized nationwide injunctions generally, it did not take issue with the Fourth Circuit's prior rulings upon which this Court relied in determining the scope of the Preliminary Injunction, including *Roe v. Department of Defense*, 947 F.3d 207 (4th Cir. 2020), which set forth principles to consider in granting an injunction to cover certain individuals similarly situated to the plaintiffs, *id.* at 231-34, and *Lord & Taylor, LLC v. White Flint, L.P.*, 780 F.3d 211 (4th Cir. 2015), which allows district courts to consider the practical difficulties of enforcement in crafting an injunction, *id.* at 217. Indeed, had *CASA de Maryland* actually overruled *Roe* and imposed new rules rendering this Court's analysis outdated to the point that a stay is warranted, the Fourth Circuit, which denied the first Motion to Stay *after* the issuance of *CASA de Maryland*, presumably have would reached a different result. *Am. Coll. of Obstetricians & Gynecologists v. U.S. Food & Drug Admin.*, No. 20-1824 (4th Cir. Aug. 13, 2020) (denying Defendants' Motion to Stay).

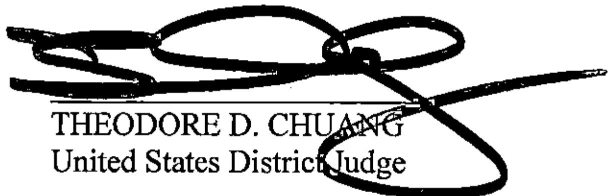
Finally, the Court notes that the general criticism of nationwide injunctions granting relief to regions and large numbers of individuals unconnected to the case is not particularly applicable to the present case. Unlike in *CASA de Maryland*, where the membership of the plaintiff organization resided in only three states and the District of Columbia, *CASA de Maryland*, 414 F. Supp. 3d at 786, here, the scope of the injunction is primarily based not on any abstract principle favoring nationwide injunctions, but on the actual geographic and professional breadth of the members of the plaintiff organizations, who are located in all 50 states and include more than 90

percent of the obstetrician/gynecologists in the United States. *See ACOG*, 2020 WL 3960625, at *33; *Richmond Tenants Org., Inc. v. Kemp*, 956 F.2d 1300, 1302, 1308-09 (4th Cir. 1992) (granting a nationwide injunction against a federal policy where the plaintiffs included a national association of tenants' organization); *see also Va. Soc'y for Human Life v. Fed. Election Comm'n*, 263 F.3d 379, 393 (4th Cir. 2001) (citing *Richmond Tenants Organization* and stating that "[n]ationwide injunctions are appropriate if necessary to afford relief to the prevailing party"). For these reasons, the Court finds no basis to alter the scope of the Preliminary Injunction at this time.

CONCLUSION

As the parties continue their ongoing dispute over the validity of the Preliminary Injunction and whether it should presently remain in effect, the Court notes that it is not open-ended. The Preliminary Injunction is slated to end 30 days after the end of the public health emergency declared by the Secretary. With the positive news relating to vaccines, there is reason to hope that day will come soon. At this time, however, as the entire nation goes through what the Coordinator of the White House Coronavirus Task Force has deemed the "most deadly phase of the pandemic," Reingold Decl. ¶ 18, the Court concludes that Defendants have not identified changed circumstances sufficient to warrant a stay or dissolution of the Preliminary Injunction, in whole or in part. Accordingly, Defendants' Renewed Motion to Stay the Preliminary Injunction and for an Indicative Ruling Dissolving the Preliminary Injunction will be DENIED. A separate Order shall issue.

Date: December 9, 2020



THEODORE D. CHUANG
United States District Judge