IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS, *et al*., Plaintiffs, vs. UNITED STATES FOOD AND DRUG ADMINISTRATION, *et al*., Defendants.	CIV. NO. 20-1320-TDC

PLAINTIFFS' BRIEF IN OPPOSITION TO DEFENDANTS' RENEWED MOTION TO STAY THE PRELIMINARY INJUCTION AND FOR AN INDICATIVE RULING DISSOLVING THE PRELIMINARY INJUNCTION

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I. INTRODUCTION

Defendants' motion to stay or dissolve the preliminary injunction on the ground that all of the risks and hardships this Court identified in July have since been "removed or significantly mitigated," Defs.' Mem. 21, is violently out of touch with reality. On October 30, the day Defendants filed their motion, approximately 100,000 people in the United States were diagnosed with COVID-19—a new global record—and nearly 1,000 people died from it. The United States broke its own record days later, and then again and again; on November 12, a staggering 194,000 new cases were reported in a single day. The number of new COVID-19 infections in *just the two weeks since Defendants filed their motion* is the same as the total number of cases when Plaintiffs first filed their Complaint at the end of May. *See* Dkt. 1, ¶ 1 ("In the four months since the first U.S. case was reported, more than 1.5 million people have been infected.").

COVID-19 hospitalizations are at an all-time high, and the number of deaths per day is much greater now than when this Court entered the preliminary injunction: according to the U.S. Centers for Disease Control and Prevention ("CDC"), the seven-day average for COVID-19 deaths per day was 1,136 on November 12, compared to 726 on July 13. Nevertheless, and even as the nation's top infectious disease experts warn that the country "could not possibly be positioned more poorly" for this winter and that we are entering the "most concerning and most deadly phase of this pandemic," Defendants assert that COVID-19 is now sufficiently under control to end injunctive relief. And despite Defendants' own experts at the CDC acknowledging that being Black or Hispanic is associated with dramatically higher risks of hospitalization and death from COVID-19, Defendants argue that it is no big deal to force medication abortion patients—a majority of whom are Black or Hispanic—to unnecessarily incur heightened COVID-19 risk.

There is no genuine dispute that forcing people to travel to a health center continues to impose serious COVID-19 risks. That is why the CDC still recommends that patients "[u]se

telemedicine, if available," "[t]alk to [their] doctor about rescheduling procedures that are not urgently needed," and use "mail-order, or other delivery services" for prescription medications. It is because of this ongoing risk that Defendant Azar last month renewed the nationwide COVID-19 public health emergency ("PHE"), and continues to allow patients throughout the country to obtain addictive medications like fentanyl and OxyContin® during the PHE through telemedicine, suspending the previous requirement for at least one in-person evaluation before these controlled substances may be prescribed. The ongoing nationwide threat is why the U.S. Food and Drug Administration ("FDA") has maintained its nationwide non-enforcement guidance allowing patients to forgo previously required in-person visits not only for other drugs subject to Risk Evaluation and Mitigation Strategies ("REMS") programs because of the serious risks they entail, but even for drugs that are still undergoing clinical trials, whose safety has not yet been determined.

Unable to muster a single declaration from any employee at the U.S. Department of Health and Human Services ("HHS") or the FDA to support their argument that travel and personal contact no longer pose a meaningful threat, Defendants rely on declarations from officials in seven states (several of which are already seeing sharp COVID-19 spikes), noting that their states have allowed certain businesses and services to re-open. But those local determinations are not at issue in this litigation and are not entitled to "deference." Defs.' Mem. 6-7. In any event, these re-openings do not reflect a "judgment . . . that it is safe" to resume normal activities, Defs.' Mem. 22; *accord id.* at 6-7, 18, but rather a balancing of the COVID-19 risks against the serious consequences of mass unemployment and isolation. Local decisions allowing people to *voluntarily* utilize in-person services cannot justify a federal *mandate* forcing higher-risk populations to engage in unnecessary travel and personal contact, regardless of their individual circumstances and their clinicians' judgment, as a condition of obtaining essential reproductive health care.

In contrast to the overwhelming evidence that reinstating an in-person pill pick-up requirement would seriously jeopardize patient safety, Defendants concede that they cannot identify any harm resulting from the injunction over the past four months. As the nation enters the early stages of a deadly new wave of the pandemic, the balance of hardships and public interest weigh heavily in favor of maintaining the injunction.

II. STANDARD OF REVIEW

In considering a motion to stay an injunction, the district court must consider "(1) whether the stay applicant has made a strong showing that he is likely to succeed 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).

A party seeking to dissolve a preliminary injunction must establish that the circumstances have changed sufficiently that dissolution is warranted. *Compare, e.g.*, *Stone v. Trump*, 400 F. Supp. 3d 317, 331–32 (D. Md. 2019) ("To satisfy this burden, the [moving] party must establish 'a significant change either in factual conditions or in law' that makes 'enforcement of the [preliminary injunction] . . . detrimental to the public interest.'" (quoting *L.J. v. Wilbon*, 633 F.3d 297, 305 (4th Cir. 2011)), *and Gooch v. Life Investors Ins. Co. of Am.*, 672 F.3d 402, 414 (6th Cir. 2012) ("Where 'significant changes in the law or circumstances' threaten to convert a previously proper injunction 'into an "instrument of wrong,"' the law recognizes that judicial intervention may be necessary to prevent inequities." (quoting *Salazar v. Buono*, 559 U.S. 700, 714-15 (2010))), *and Favia v. Ind. Univ. of Penn.*, 7 F.3d 332, 344 (3d Cir. 1993) (party seeking to modify preliminary injunction has "burden of demonstrating a 'significant' change in facts"), *with, e.g.*, *Canal Authority of Fla. v. Callaway*, 489 F.2d 567, 578 (5th Cir. 1974) (district court can make any changes "that are equitable in light of subsequent changes in the facts or the law, or for any

other good reason"), *and Movie Sys., Inc. v. MAD Minneapolis Audio Distribs., a Div. of Smoliak & Sons, Inc.*, 717 F.2d 427, 430 (8th Cir. 1983) (same). Ultimately, the question for the Court in considering changes to an interlocutory order is whether the requested relief is what "justice requires." *Fayetteville Invs. v. Com. Builders, Inc.*, 936 F.2d 1462, 1473 (4th Cir. 1991).[1]

III. ARGUMENT

A. With a Record-Breaking COVID-19 Resurgence Already Underway and Winter Approaching, Defendants' Argument that the Serious Risks and Burdens Justifying the Injunction Have Dissipated Lacks All Credibility and Does Not Justify a Stay or Dissolution.

Defendants' sunny picture of the state of the COVID-19 pandemic is squarely at odds with the dire warnings of their own infectious disease experts, the data reported by their own CDC, and their own extraordinary and ongoing actions to prevent unnecessary health care visits nationwide during the PHE. That some states now give people greater latitude to engage in certain optional in-person activities, Defs.' Mem. 6-7, in no way establishes that the risks and hardships that warranted the preliminary injunction have dissipated. To the contrary, the number of new COVID-19 cases reported yesterday was more than *triple* the number of new cases on the day this Court granted the injunction, and the number of deaths is significantly higher now than it was then: the CDC reports a seven-day moving average for November 12 of 1,136 deaths per day, a 56 percent increase from the July 13 seven-day average (726 deaths).[2] *See also* Second Declaration of Arthur L. Reingold, M.D. ("Second Reingold Decl."), attached hereto as Ex. 1, ¶ 7; Declaration of Mary Travis Bassett, M.D., M.P.H. ("Bassett Decl."), attached hereto as Ex. 2, ¶ 14.

[1] Plaintiffs agree with Defendants that this Court lacks authority to grant Defendants' request to dissolve or modify the injunction, and that, should this Court find that the injunction should be dissolved or modified, an indicative ruling under Fed. R. Civ. P. 62.1 would be the proper course. *See Defs.' Mem.* 3 (citing *Doe v. Pub. Citizen*, 749 F.3d 246, 258 (4th Cir. 2014)).

[2] Ctrs. for Disease Control & Prevention, Coronavirus Disease 2019 (COVID-19), CDC COVID Data Tracker, Trends in Number of COVID-19 Cases and Deaths in the US Reported to CDC, by State/Territory (Nov. 13, 2020), https://covid.cdc.gov/covid-data-tracker/#trends_dailytrendscases [hereinafter "CDC Data Tracker"].

Defendants fall far short of the requisite "strong showing" that the risk of COVID-19 is no longer a substantial obstacle to abortion access, *Hilton*, 481 U.S. at 776, much less demonstrate that "justice requires" forcing a population disproportionately likely to be hospitalized and die from COVID-19 to incur needless risk—and to put their families at needless risk—by traveling to a health center during the PHE for the sole purpose of picking up a pill and signing a form, *Fayetteville Invs.*, 936 F.2d at 1473.

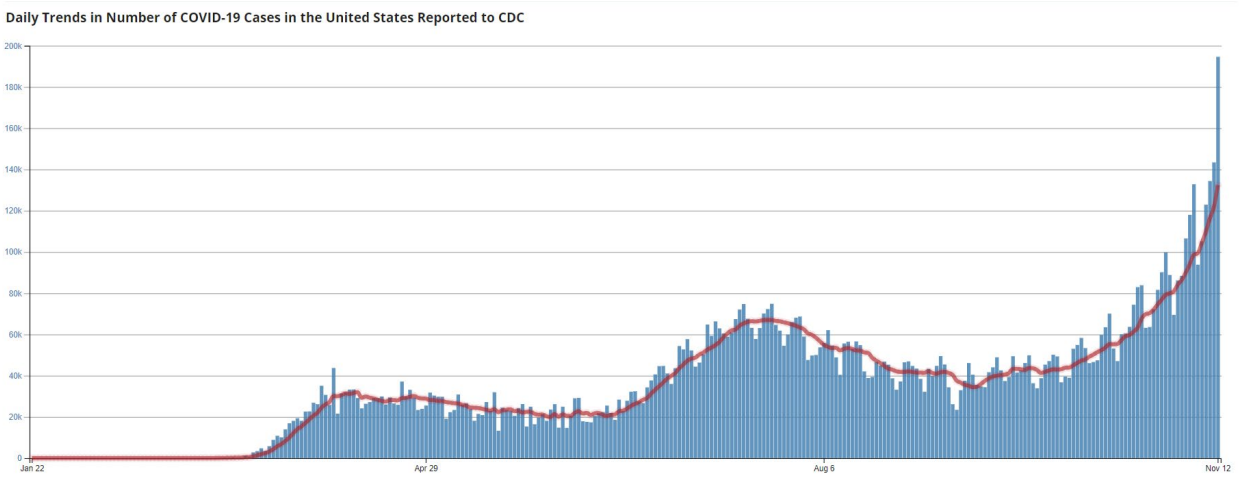
1. Defendants' Suggestion that COVID-19 is Under Control Turns Reality on Its Head.

Eight months into the pandemic in the United States, more than 10 million people have been infected, Second Reingold Decl. ¶ 7, a more than three-fold increase since July, *see* Mem. Op., Dkt. 90, 8. Nearly 240,000 people in the U.S. have died—four times as many American deaths as in the Vietnam War. Second Reingold Decl. ¶ 7. While the medical community's understanding of the novel coronavirus SARS-CoV-2 and the disease it causes, Coronovirus Disease 2019 ("COVID-19"), has grown since July, and experts have identified certain measures that can help reduce the virus's spread—including social distancing, mask-wearing, and hand-washing—the United States still has not been able to limit transmission. *Id.* ¶¶ 6-12; Bassett Decl. ¶ 12. The opposite is true: the number of new cases per day has more than tripled since this Court entered the injunction, with case numbers currently rising in 46 states.[3] Second Reingold Decl. ¶¶ 7-8.

On October 30, the date on which Defendants filed this motion, approximately 100,000 people in the United States were newly diagnosed with COVID-19—at the time, a world record for most single daily infections. *Id.* ¶ 7; Bassett Decl. ¶ 12. The nation suffered one million new COVID-19 cases in just the ten days following Defendants' filing of this motion, Second Reingold Decl. ¶ 7, and rates are rapidly accelerating: the CDC reported nearly *200,000* new cases on

[3] CDC Data Tracker, *supra note* 2.

November 12 alone.[4] While Defendants argue that "[t]he precautionary measures that Americans are now aware of and have access to," like mask-wearing or hand-washing, mean that transmission risks are now minimal, *see* Defs.' Mem. 7, a visual from Defendants' own CDC shows that this could not be farther from the truth:[5]



Public health experts have long predicted a winter resurgence. Second Reingold Decl. ¶¶ 14-18; Bassett Decl. ¶ 15; *see also* First Declaration of Arthur L. Reingold, M.D., Dkt. 11-4, ¶¶ 24-29. There is now definitive evidence that the virus can be spread not only through respiratory droplets within six feet, but also through airborne transmission. Second Reingold Decl. ¶¶ 15, 27-29; Bassett Decl. ¶ 32. Viral particles emitted when an infected person talks, breathes, coughs, sneezes, or sings can remain suspended in the air and potentially travel distances greater than six feet, then be inhaled by someone else. Second Reingold Decl. ¶¶ 15, 29; Bassett Decl. ¶ 32. As the CDC acknowledges, such transmission is more common indoors, particularly in areas with poor ventilation. Second Reingold Decl. ¶ 15. Thus, as the weather cools across much of the United States and people spend more time congregating indoors, there will be even greater transmission. *Id.*; Bassett Decl. ¶¶ 15-16. This will likely be exacerbated by holiday travel and by pandemic

[4] *Id.*
[5] *Id.*

fatigue, both leading people to relax their adherence to social distancing guidelines. Second Reingold Decl. ¶¶ 15-16; Bassett Decl. ¶¶ 15-16. Moreover, the overlap with seasonal influenza, another highly contagious and often severe respiratory illness, may overwhelm health care providers across the country, placing strains on staffing and hospital beds and jeopardizing COVID-19 patients' prognoses. Bassett Decl. ¶ 16; Second Reingold Decl. ¶ 17.

In sharp contrast to Defendants' vague assurances that states "have weathered rising and falling COVID-19 rates, but . . . continue to move forward," Defs.' Mem. 24, the nation's leading infectious disease experts warn of a devastating chapter ahead. The day before Defendants filed this motion, Dr. Anthony Fauci, director of the National Institute of Allergy and Infectious Diseases at the National Institutes of Health within Defendant HHS, warned that the United States needs to make an "abrupt change" to improve public health practices. Second Reingold Decl. ¶ 18. According to Dr. Fauci, the country is "in for a whole lot of hurt. . . . All the stars are aligned in the wrong place as you go into the fall and winter season . . . . You could not possibly be positioned more poorly." *Id.* On November 2, Dr. Deborah Birx, coordinator of the White House Coronavirus Task Force, reported to White House and federal agency officials that "[w]e are entering the most concerning and most deadly phase of this pandemic . . . leading to increasing mortality." *Id.*

Indeed, we still have no established and accessible treatment. *Id.* ¶¶ 35-36. There is one experimental treatment (remdesivir), available only to hospitalized patients and only at certain hospitals, which may somewhat improve the prognosis for severely ill patients. *Id.* ¶ 35; Bassett Decl. ¶ 26. And the FDA recently gave emergency authorization for an experimental treatment (bamlanivimab) that may help prevent severe illness and death, but is accessible to few: bamlanivimab must be administered intravenously in specially equipped health care settings; it has only been authorized for use in a subset of patients at high risk for severe illness or death; and, at

least for the next few months, the supply is very limited. Second Reingold Decl. ¶ 36. That is all.

While, thankfully, it appears that there is progress toward the development and approval of a vaccine, experts agree that it will still be some time before there is widespread availability and use. *Id.* ¶¶ 19-23; Bassett Decl. ¶¶ 17-18. In the meanwhile, the nation continues to suffer. The numbers of daily deaths from COVID-19 are far higher than they were even in July, and the number of current hospitalizations for COVID-19 is higher than it has been at any point since the start of the pandemic. Bassett Decl. ¶¶ 13-14.

Thus, notwithstanding Defendants' observations about mask mandates and increased testing, *see* Defs.' Mem. 6-10, neither intervention has managed to stem transmission. And while treatment measures have improved somewhat, leading experts—including scientists, physicians, and public health officials employed by Defendant HHS—predict a deadly chapter ahead. *See* Second Reingold Decl. ¶ 18. Defendants' suggestion that Plaintiffs are no longer likely to prevail on their undue burden claim in light of our "[g]reater medical understanding of COVID-19," Defs.' Mem. 4, is contradicted by the overwhelming evidence.

2. Abortion Patients Will Continue to Face Serious Risks if Forced to Travel Unnecessarily to a Health Center During the Pandemic.

Defendants argue that "[t]he precautionary measures that Americans are now aware of and have access to"—specifically, mask-wearing and increased testing—"have mitigated the risks of travel such that an individual trip does not increase the risk of contracting COVID-19 beyond that individual's baseline risk." Defs.' Mem. 7; *see also id.* at 6, 8-10. This is plainly false.

First, every trip outside the home, and every interaction with other people, adds risk. Bassett Decl. ¶¶ 28-30, 35; Second Reingold Decl. ¶ 25.[6] And, unless accompanied by robust

[6] This is true even in communities reporting low local COVID-19 rates at the time of the trip or interaction; it is only after many people become infected that people become aware that they were living in or traveling through a "hot spot." Second Reingold Decl. ¶ 43.

quarantining and contact tracing programs and rapid turnaround of results, testing is of only limited use as a preventive tool, Second Reingold Decl. ¶ 12—as evidenced by the skyrocketing infection rates across the country despite significantly increased test numbers, *see* Defs.' Mem. 9-10.

Defendants' suggestion that the increased use of masks means that "a one-time trip to a medical facility does not present heightened risk," Defs.' Mem. 19; *see also id.* at 18, is dangerously misguided. While masks are an important tool in reducing COVID-19 transmission at the population-level, with the exception of N95 masks (which are generally only available to health care providers), masks are—in the CDC's words—"primarily intended" to prevent the wearer from infecting other people. Bassett Decl. ¶ 33; Second Reingold Decl. ¶ 31. While wearing a mask can "also help reduce inhalation" of viral particles, the CDC notes that even cloth masks of the highest quality (with multiple layers of cloth with high thread count) still only filter out fewer than 50 percent of fine particles; in other words, they can reduce but do not eliminate the risk of infection. Bassett Decl. ¶ 33; Second Reingold Decl. ¶ 31.

The extent of the risk that an individual faces on any "individual trip" is dictated largely by the uncontrollable actions of the people with whom they cross paths: specifically, whether *others* have a mask made of appropriate material and are wearing it properly (securely covering both their nose and mouth) at that time. Bassett Decl. ¶ 33; Second Reingold Decl. ¶ 31. For abortion patients, many of whom have to travel long distances to get to the nearest abortion provider, *see* Declaration of Allison Bryant Mantha, M.D., M.P.H., FACOG ("Bryant Decl."), Dkt. 11-3, ¶ 22 (89 percent of U.S. counties lack an abortion provider), there is a higher likelihood that patients will be exposed to people who are not consistently and properly wearing masks (for instance, while they eat or drink), *see* Bassett Decl. ¶ 33. In short, masks do not provide assured protection to any individual on any individual trip. *Id.*; Second Reingold Decl. ¶ 31.

Second, abortion patients face heightened risk of viral exposure if forced to travel to a health center to pick up their mifepristone, because abortion patients, who are predominantly low-income and people of color, are less likely to own a private vehicle and thus more likely to have to travel in a car or other enclosed space with others. Mem. Op. 14, 47; *see also* Bassett Decl. ¶¶ 30-31. Since July, the evidence of aerosolized transmission has become unequivocal; the risks of sitting in a shared car, bus, or train are now even more certain. Second Reingold Decl. ¶¶ 27-31; Bassett Decl. ¶ 32. We also now know that a person traveling in a shared vehicle can become infected by someone sitting several rows away—or even by someone who coughed or sneezed in the vehicle before the patient entered. Bassett Decl. ¶ 32; Second Reingold Decl. ¶¶ 29-31.

For the same reasons, the increased (albeit partial and often temporary, *see infra* pp. 17-18) school and childcare options available in some locations do not mean that the 60 percent of abortion patients with children, Mem. Op. 14, do not continue to incur risks for themselves and their families if compelled to drop their children off for care, or bring their children with them, while they travel unnecessarily to a health center, *see e.g.*, Bassett Decl. ¶ 34; Third Declaration of Honor MacNaughton, M.D. ("Third MacNaughton Decl."), attached hereto as Ex. 3, ¶¶ 6-8.

Third, it is even clearer now than it was in July that abortion patients face great risk of suffering severe illness, hospitalization, and death if they contract COVID-19 on this journey. *See* Bassett Decl. ¶¶ 19-27; Second Reingold Decl. ¶ 5. COVID-19 hospitalizations are at an all-time high, Bassett Decl. ¶ 13; the average number of daily deaths is more than 50 percent higher than it was in mid-July, *id.* ¶ 14;[7] and people of color, who comprise a majority of abortion patients, are vastly more likely to suffer these severe consequences if they contract the disease, *id.* ¶¶ 19-23, 27; *see also* Second Reingold Decl. ¶ 34. According to the CDC, non-Hispanic Black,

[7] CDC Data Tracker, *supra note* 2.

Hispanic/Latinx, and Indigenous people are all more than *four and a half times as likely* as non-Hispanic white people to be hospitalized with severe illness from COVID-19. Bassett Decl. ¶ 23. Looking only at a reproductive age population, the disparities are even greater. Black and Hispanic people ages 25-34 are more than *700 percent* more likely to die from COVID-19 than white people in the same age range, and approximately *900 percent* more likely to die from COVID-19 between the ages of 35 and 44. *Id.* ¶ 21. Defendants' suggestion that the In-Person Requirements are now constitutionally valid because, "[e]ven in the event that a[n] [abortion patient] were to contract or spread SARS-CoV-2, the virus that causes COVID-19, the prognosis for COVID-19 patients has improved," is as wrong as it is cruel. Defs.' Mem. 10.

Moreover, mortality is not the only serious consequence COVID-19 threatens. Second Reingold Decl. ¶¶ 32-37; Bassett Decl. ¶ 23. A number of studies have found that some people with COVID-19 suffer long-term, and in some cases serious, consequences even after recovering from their initial illness. Second Reingold Decl. ¶ 37. The long-term consequences can include difficulty breathing and shortness of breath, gastrointestinal problems, brain fog, and chronic fatigue, and these symptoms can persist for weeks and even months after COVID-19 illness. *Id.* Dr. Fauci has stated that "there's no question that there are a considerable number of individuals who have a postviral syndrome that really, in many respects, can incapacitate them for weeks and weeks following so-called recovery and clearing of the virus." *Id.* Women appear to be four times more likely to suffer these long-term health consequences. *Id.*

Defendants' principal argument is that the risks of traveling to a health center "are no different from the risks associated with any other outing outside the home, such as going to the store, picking up food, or engaging in any other activities that involve travel." Defs.' Mem. 9. Yet the CDC continues to recommend that people avoid all of those activities because of the undisputed

viral risks they impose. Bassett Decl. ¶ 35. Current CDC guidance still urges people to "limit visiting the grocery store, or other stores selling household essentials, in person," and instead "[o]rder groceries and other items online for home delivery or curbside pickup (if possible)."[8] And, tellingly, the CDC still recommends that patients "[u]se telemedicine, if available," "[t]alk to [their] doctor about rescheduling procedures that are not urgently needed," and use "mail-order, or other delivery services" for prescription medications.[9]

As public health experts recognize, it is one thing to permit people to ignore ongoing CDC recommendations to have their prescriptions and groceries delivered, and let them choose to incur the indisputable risks associated with in-person activities. It is quite another to *mandate* that all medication abortion patients, a population at heightened risk of both exposure to and serious health consequences from COVID-19, travel to pick up a pill that they could otherwise safely receive by mail. *See id.* ¶¶ 41-42; Second Reingold Decl. ¶ 45.

3. Defendants' Renewals of the National COVID-19 PHE and Nationwide Suspensions of Other In-Person Requirements Belie Their Argument that Travel No Longer Poses a Substantial Obstacle.

Defendants' position that the injunction should be lifted because COVID-19 is no longer a serious threat nationwide is impossible to square with their own actions. This Court scheduled the injunction to end when Defendant Azar declares that the nationwide PHE is over. Dkt. 92, ¶ 2. But far from declaring COVID-19 defeated, just last month, Defendant Azar renewed the PHE for a third time in recognition of the pandemic's "continued consequences." Declaration of Ameet

[8] Ctrs. for Disease Control & Prevention, Coronavirus Disease 2019 (COVID-19), Running Essential Errands: Grocery Shopping, Take-Out, Banking, and Getting Gas (Sept. 11, 2020), https://www.cdc.gov/coronavirus/2019-ncov/daily-life-coping/essential-goods-services.html.

[9] Ctrs. for Disease Control & Prevention, Coronavirus Disease 2019 (COVID-19), Doctor Visits and Getting Medicines (Sept. 11, 2020), https://www.cdc.gov/coronavirus/2019-ncov/daily-life-coping/doctor-visits-medicine.html.

Sarpatwari, Ph.D, J.D. ("Sarpatwari Decl."), attached hereto as Ex. 4, ¶ 10.[10] And he did so on a "nationwide" basis, despite having authority to limit a PHE declaration to only certain areas. *Id.*[11]

Nor have Defendants withdrawn or narrowed any of the "extraordinary" nationwide policies and guidance they implemented this spring to encourage the use of telemedicine and limit in-person visits for medical care. Mem. Op. 42-45. As this Court found, Defendants have expanded Medicare coverage for telehealth, loosened HIPAA restrictions to more readily permit remote care, and relaxed in-person requirements associated with numerous drugs so that patients can obtain care without the need to travel to health care facilities. Since July, Defendants have maintained, renewed, and updated these policies: all remain in effect nationwide. Sarpatwari Decl. ¶ 11.

The callous and arbitrary inconsistency of Defendant's position that abortion patients alone must engage in unnecessary travel during the pandemic is laid bare by the fact that Defendants have suspended in-person requirements for other drugs that are far more dangerous than mifepristone. *Id.* ¶¶ 9, 12, 14-16, 19-20, 23-25. For example, Defendants are continuing to permit doctors nationwide to prescribe drugs such as fentanyl, oxycodone, and other schedule II controlled substances—all of which carry lethal risks of misuse and abuse—without ever meeting their patient in person. *Id*. ¶¶ 13-15. And they have maintained this waiver notwithstanding that 45,000 opioid-involved overdose deaths were recorded in the United States in 2018 alone, a

[10] As noted above, though there have been recent encouraging advances toward development of a vaccine, the nation is still, in the best-case scenario, several months away from widespread availability and use. *See* Second Reingold Decl. ¶¶ 19-23; Bassett Decl. ¶¶ 17-18. When we reach that point, Defendants will be free either to lift the PHE (triggering the termination of the preliminary injunction) or return to this Court to argue that relevant circumstances have changed such that the preliminary injunction should be lifted. But neither justice nor the public interest would be served by preemptively dissolving the preliminary injunction well before a vaccine is available, as the nation shatters global COVID-19 records and winter approaches. *See supra* pp. 5-7; *see Fayetteville Inv'rs*, 936 F.2d at 1473; *Stone*, 400 F. Supp. 3d at 332.

[11] *Compare* U.S. Dep't of Health & Hum. Servs., Renewal of Determination that a Public Health Emergency Exists (Oct. 2, 2020), https://www.phe.gov/emergency/news/healthactions/phe/Pages/covid19-2Oct2020.aspx, *with, e.g.*, U.S. Dep't of Health & Hum. Servs., Renewal of Determination that a Public Health Emergency Exists in Puerto Rico as a Consequence of the Zika Virus Outbreak (Aug. 12, 2016), https://www.phe.gov/emergency/news/healthactions/phe/Pages/zika-pr.aspx.

lethality rate so extreme that "overdoses from prescription opioids . . . [have] reduc[ed] life expectancy in the United States." *Id.* ¶ 14. The societal "costs for opioid use disorder and fatal opioid overdose in 2017 were estimated to be $1.02 trillion," and even today the FDA declares that "[o]ne of [its] highest priorities . . . is advancing efforts to address the crisis of misuse and abuse of opioid drugs harming families." *Id.*[12] Nevertheless, Defendant Azar has lifted the in-person evaluation requirement for opioids in recognition of the COVID-19 risks of travel.

Defendants also continue to permit clinicians to relax REMS in-person testing requirements during the PHE for drugs like the antipsychotic clozapine. *Id.* ¶¶ 18-19. The FDA required a REMS program because clozapine can induce neutropenia (an abnormally low number of a certain kind of white blood cells known as neutrophils), which in severe cases "can lead to serious and fatal infections," as stated in clozapine's FDA-approved black-box warning. *Id.* ¶ 19. Because of these potentially lethal harms, the REMS program for clozapine requires routine monitoring and reporting of patients' absolute neutrophil count. *Id.* Yet despite these serious risks, because of the dangers inherent in traveling to a health care facility for testing, the FDA continues to maintain a nationwide non-enforcement policy that permits clinicians to prescribe clozapine without the routine testing otherwise mandated by the REMS. *Id.* ¶¶ 18-20.

Moreover, in a nationwide guidance just updated in September, the FDA authorized health care professionals to modify study protocols to avoid in-person visits for drugs in clinical trials. *Id.* ¶ 22. In other words, the FDA deems the risks of COVID-19 so great that it permits researchers to use alternative approaches (including home delivery) to protect patients from traveling to clinical sites to obtain drugs and drug products that have *not even been approved for safe use* in

[12] U.S. Food & Drug Admin., Opioid Medications (Aug. 4, 2020), https://www.fda.gov/drugs/information-drug-class/opioid-medications.

the United States. *Id.* at ¶ 23-24. Yet Defendants ask this Court to reinstate the In-Person Requirements for mifepristone, a drug whose safety and efficacy is "well-established" after more than two decades of FDA approval. *See* Bryant Decl. ¶ 41; *see also id.* at ¶ 42 (FDA admission that major adverse events are "exceedingly rare").

Defendants' actions with regard to other, far less safe, medications evidence their understanding of the ongoing nationwide risks posed by travel and personal contact during the COVID-19 PHE, and are dispositive of this motion.

4. Abortion Patients Continue to Face Particular Challenges Paying for and Arranging Transportation and Childcare During the Pandemic.

Defendants also argue that the hardships abortion patients face in paying for and arranging transportation and childcare during the pandemic have all been "removed or significantly mitigated," Defs.' Mem. 21, because states and localities have (1) permitted more businesses to re-open, which offers "greater economic opportunity" than existed in July, Defs.' Mem. 19-20, and (2) permitted some schools and childcare facilities to fully or partially re-open, *id.* at 14-18.

Even on its own terms, Defendants' anecdotal evidence of improvement would not be enough to carry their burden: that unemployment rates are less devastating and some localities are permitting students to return "for some form of in-person instruction" hardly establishes that the hardships have dissipated. Defs.' Mem. 15, 20. But Defendants' sanguine portrait of a nation recovered is also profoundly incomplete and misleading. As detailed below, the state of the economy remains very poor, particularly for women, people of color, and low-income people; the availability of in-person schooling is hit-or-miss and often contingent on stable or falling COVID-19 rates in the region; and even where daycare options are available, low-income families are more likely to be disqualified from or unable to afford them during the pandemic. Abortion patients, three out of four of whom are low-income and 53 percent of whom are Black or Latinx, *see* Bryant

Decl. ¶¶ 18-19, will continue to disproportionately suffer these hardships, Declaration of Trevon Logan, Ph.D. ("Logan Decl."), attached hereto as Ex. 5, ¶ 24.

While the unemployment rate has declined since its peak in April, it was still twice as high last month as it was in February 2020. *Id.* ¶ 12. Today, nearly 11 percent of Black Americans are unemployed, up from 5.5 percent at this time last year. *Id.* ¶ 26 & n.26. The unemployment rate does not even capture people who are employed only part time because of reduced hours or demand or because they could not find a full-time position: the number of such *under*-employed people increased by 383,000 in October alone, for a total of 6.7 million people. *Id.* ¶ 15. And neither of these measures accounts for people who are not actively looking for a job, for instance because of increased caretaking responsibilities during the pandemic. *Id.* ¶ 16. Women, who were overrepresented in many industries hit hard by COVID-19 and have disproportionately carried the unique childcare burdens of the pandemic, have left the labor force in droves—865,000 in September alone, accounting for 80 percent of exits from the job market that month. *Id.* ¶ 27.

Other indicators of individuals' financial health fill out this picture. Last month, nearly one in three adults in the United States reported difficulty paying ordinary household expenses, such as food and housing costs, car and loan payments, or medical bills, over the past seven days. *Id.* ¶ 21. One in ten U.S. adults reported that their household sometimes or often did not have enough to eat over the previous seven days. *Id.* Black and Hispanic households, in particular, are experiencing heightened rates of food insecurity and housing distress during this crisis. *Id.* ¶ 26.

For people struggling to put food on the table or keep a roof over their heads, it will continue to be extremely difficult, if not impossible, to pay for unexpected transportation and/or childcare expenses—and particularly for transportation methods like Uber, which may be somewhat safer during the pandemic (because fewer people enter the vehicle) but are far more

expensive. *Id.* ¶ 36. For the 35 percent of abortion patients who have to travel 25 miles or more to the nearest provider, *see* Bryant Decl. ¶ 22, these transportation costs are particularly likely to be prohibitive during an economic crisis, *see* Logan Decl. ¶ 36.

State re-openings have had only a modest impact on economic activity and are not a reliable indicator of recovery. *Id.* ¶ 30. Consumer spending and employment, particularly in industries like restaurants, travel, and hospitality that provide in-person services, are still well below pre-pandemic levels despite some re-openings. *Id.* For low-wage workers, who saw a far greater initial employment drop at the start of the pandemic as compared to higher-wage earners, and who have been far slower to rebound, employment levels are still down 17 percent as compared to January. *Id.* ¶ 25. Furthermore, the economic impact of state re-openings is unlikely to be uniform or consistent, particularly this winter. *Id.* ¶ 31; *see also* Second Reingold Decl. ¶¶ 15-16. As infection rates rise, many jurisdictions are already beginning to slow or pause re-opening plans—or even to re-impose restrictions that had been lifted during the summer and early fall. Logan Decl. ¶ 31.

Childcare and schooling are likewise far from any return to normalcy, with many major jurisdictions having never re-opened schools and others reversing plans to allow in-person instruction. *See id.* ¶ 33; *see also* Defs.' Mem. 15 & n.32 (describing substantial variations in the availability of even part-time in-person schooling as of October 30). For example, in Columbus, Ohio, schools planned to re-open for in-person classes in November, but re-opening was postponed until at least January 2021 due to concerns about increasing rates. Logan Decl. ¶ 33. Boston reversed course on in-person schooling last month, as did Philadelphia and several districts in the Chicago area. Logan Decl. ¶ 33; Bassett Decl. ¶ 40; Third MacNaughton Decl. ¶ 7. In early October, shortly after re-opening, New York City officials announced closures of schools and daycares in multiple neighborhoods in Brooklyn and Queens following COVID-19 outbreaks.

Logan Decl. ¶ 33. Many Maryland schools never re-opened, and outbreaks have similarly caused a number of school districts to postpone or alter their plans for in-person schooling. *Id.*

Even where daycare centers are open, it is more difficult now than pre-pandemic for abortion patients to afford and access these services. *Id.* ¶¶ 34, 36. The challenges that low-income communities and communities of color faced finding affordable daycare even before the pandemic are likely to have been exacerbated by the job losses and financial insecurity that followed the economic downturn. *Id.* ¶ 34. And families in which any household member has been exposed to COVID-19 may be disqualified from bringing their child to a daycare center—a particular barrier for low-income people and people of color, who are more likely to live in crowded households containing multiple people who face heightened COVID-19 exposure at work, on public transportation, and in their communities more generally. *Id.* ¶ 35.

For low-wage workers, whose work schedules are often unpredictable, the halting and inconsistent availability of childcare and in-person schooling will exacerbate the challenge of scheduling an in-person appointment for medication abortion care. *See id.* ¶ 33; *see also* Third MacNaughton Decl. ¶¶ 6-8. Choreographing these in-person appointments—which are already less available because of reduced capacity during the pandemic, and likely to see further reductions in capacity during the winter surge—will continue to delay some patients' access to this time-sensitive care, or block access altogether. *See* Third MacNaughton Decl. ¶¶ 5-6, 11 (describing patients who would have had to delay their appointments if not for the injunction).[13]

Particularly as we enter the winter COVID-19 resurgence, Defendants' assurances that the

[13] Defendants assert that small increases in the absolute numbers of abortions provided in two states, Indiana and Nebraska, in 2020 as compared to 2019 prove that patients nationwide are not struggling to access in-person abortion care during the pandemic. *See* Defs.' Mem. 13-14. This facile argument not only lacks any scientific rigor, but also ignores the undisputed evidence that abortion *demand* is up due to widespread job losses, disrupted access to contraception, and the other extraordinary hardships people are facing during the pandemic and associated economic crisis. *See* Bryant Decl. ¶ 20; Logan Decl. ¶¶ 12-17, 19-30, 34, 36-38.

economic hardships and unique childcare challenges caused by the pandemic have been mitigated are not supported by the weight of the evidence. To the contrary, abortion patients are likely to continue to have significant difficulty raising funds and arranging transportation and childcare for an in-person visit to pick up their mifepristone pill and sign a form.

5. States' Decisions to Permit Some In-Person Activities Cannot Justify a Federal Travel Mandate for All Medication Abortion Patients.

As this Court already found, and as remains true, the FDA "has provided no sign that it has undertaken a formal review of the [In-Person Requirements] in light of the now widespread use of telemedicine and the ongoing pandemic." Mem. Op. 53. And Defendants are *still* unable to marshal a single declaration from any HHS or FDA expert that travel and in-person activities do not pose significant COVID-19 risks.

Instead, Defendants resort to asking for "deference" to the inapposite determinations of state officials not to bring their local economies to a full halt. Defs.' Mem. 6-7. Those state decisions are not at issue in this litigation and do nothing to help Defendants' cause. In Defendants' telling, state orders allowing certain businesses and services to resume during the pandemic reflect a "judgment[] . . . that it is safe" to resume in-person activities. *Id.* at 7; *accord id.* at 6, 8, 22. But these determinations instead reflect a balancing of the ongoing COVID-19 risks against economic needs and other imperatives, as Defendants' own witnesses concede. Bassett Decl. ¶¶ 36-39; Second Reingold Decl. ¶¶ 38-40; *see also* Defs.' Mem. Ex. 1, Dkt. 141-4, ¶ 12 ("I have also worked with other state agencies to balance medical access, public safety, law enforcement, and economic needs during the pandemic."); *id.* at Ex. 3, Dkt. 141-6, ¶ 3 ("NDHHS has sought to balance many interests and needs during this COVID-19 pandemic. These include (1) the need to ensure that patients have access to medical care and (2) the interest in avoiding unnecessary burdens on economic activity and personal liberty."); *id.* at Ex. 6, Dkt. 141-9, ¶ 16 ("We continue to work

every day to protect the lives and health of Oklahomans, as well as their livelihoods.").

While national lockdowns would be the surest way to prevent COVID-19 transmission—and indeed, that is the strategy now being adopted again in some European countries in response to their COVID-19 resurgences—there is a wide understanding that the costs of mass unemployment and enforced isolation are severe, and pose other serious public health consequences. Bassett Decl. ¶¶ 36, 38; Second Reingold Decl. ¶¶ 38-40, 42. Today, because of the economic crisis caused by the pandemic, millions of families are struggling to afford food and shelter. Logan Decl. ¶¶ 21, 26, 36; Bassett Decl. ¶ 38. Children with special needs are falling far behind without in-person learning opportunities. Second Reingold Decl. ¶ 39; Bassett Decl. ¶ 38. People isolated at home are suffering mental health crises, and concerns about child maltreatment and domestic violence grow. Bassett Decl. ¶ 38. In the face of these multiple crises, that state and local officials have permitted certain businesses and services to resume (at least partially and for the moment) does not mean that an individual engaging in those in-person activities will not become infected and, in turn, suffer severe illness. *Id.* ¶¶ 36, 38-39; Second Reingold Decl. ¶¶ 38-41, 44. The nation's soaring infection rates make that perfectly clear. *See supra* pp. 5-6.

Moreover, there is an enormous difference between allowing certain businesses and services to re-open for people to *voluntarily* utilize during the pandemic (despite ongoing CDC recommendations to avoid in-person activities), as opposed to a *mandate* forcing a higher-risk population to engage in unnecessary travel and interactions regardless of their circumstances and their clinicians' medical judgment. Bassett Decl. ¶¶ 41-42; Second Reingold Decl. ¶ 45.

Defendants' reliance on *South Bay United Pentecostal Church v. Newsom* turns that case upside down. *See* Defs.' Mem. 7, 22 (citing 140 S. Ct. 1613, 1613-14 (2020)). Unlike in *South Bay*, where the Supreme Court declined to enjoin a state order restricting certain gatherings in

order to *mitigate* COVID-19 spread, 140 S. Ct. at 1614 (Roberts, C.J., concurring in denial of application for injunctive relief), here, Defendants defend a pre-pandemic requirement that they *never reevaluated* in light of the exigencies of the public health emergency, even while suspending in-person requirements for other, far less safe medications during the COVID-19 PHE.

In sum, the decisions by state officials to permit partial, optional re-openings are irrelevant to the resolution of this motion. The more apt analogies are to Defendants' nationwide suspensions of other in-person mandates during the PHE (including mandatory in-person medical consultations for opioids), which reflect Defendants' determination that the threat of COVID-19 outweighs even the far more severe safety concerns associated with drugs like fentanyl and OxyContin®.

B. Defendants Can Offer No Evidence of Harm After Four Months of the Injunction, and the Balance of Hardships and Public Interest Strongly Favor Retaining the Injunction as the Public Health Crisis Grows.

Defendants can neither establish that retaining the preliminary injunction will harm them or the public, nor credibly counter the overwhelming evidence that reinstating the In-Person Requirements would place countless people—medication abortion patients across the country, as well as their families and communities—at unnecessary life-threatening risk during the ongoing pandemic. Unable to point to a single patient who has been harmed during the four months the injunction has been in place, the most Defendants can offer is that "actual harm is not relevant," Defs.' Objs. & Resps. to Pls.' Disc. Reqs., attached hereto as Ex. 6, 4. This Court already found that the In-Person Requirements "do not advance general interests of patient safety and thus constitute 'unnecessary health regulations,'" Mem. Op. 51 (quoting *Whole Woman's Health v. Hellerstedt*, 136 S. Ct. 2292, 2309 (2016)), and Defendants cannot provide a shred of evidence after four months of the injunction to cast doubt on that conclusion. *Contra* Third MacNaughton Decl. ¶ 10 (discussing smooth and safe implementation of the injunction).

The evidence is overwhelming and indisputable that COVID-19, and the economic crisis

it has caused, remain a profound threat. Defendant Azar has renewed the national COVID-19 public health emergency, and Defendants HHS and FDA have retained all suspensions of other in-person requirements, as cases rise in 46 states and daily national case numbers more than triple their height in July. *See supra* pp. 5-6. Defendants' own experts ominously predict that the country "could not possibly be positioned more poorly" for the winter and that we are entering the "most deadly" phase of the pandemic, and CDC data confirm that the coming illnesses and loss of life will be borne disproportionately by people of color. *See supra* pp. 7, 10-11. In the past month, numerous school districts have done about-faces on in-person instruction in response to spiking rates. *See supra* pp. 17-18. Unemployment levels remain twice as high as in February, and nearly one in three Americans is struggling to pay basic expenses like food and rent. *See supra* p. 16.

Defendants cannot contest these facts. The balance of hardships and public interest weigh heavily in favor of retaining protections against needless COVID-19 risks by allowing medication abortion patients to continue to receive their mifepristone by mail or delivery under the supervision of a certified prescriber.

C. The Injunction Is Properly Tailored and Defendants Have Not Identified Any Feasible Way of Narrowing It.

Defendants argue that the injunction should be narrowed in light of "[v]ariations in infection rates across geography and time," Defs.' Mem. 24, yet concede that rates will continue to ebb and flow unpredictably within any given state—one of the key factual bases for this Court's remedy. *See* Mem. Op. 77 (noting that "Dr. Reingold's expert opinion that there would be 'resurgences of COVID-19' across the United States during 2020 . . . has already proven to be correct"). This Court already found "that crafting relief that attempts to account for both the unpredictable changes and nuanced regional differences [of the pandemic] across 50 different states over an extended period of time is simply infeasible," *id.* at 77-78, and Defendants offer no

feasible way to do so now. Indeed, Defendants' own evidence underscores the rapidly evolving data: *all* seven of the states from which Defendants submitted declarations just two weeks ago proclaiming their improving status now face rising positivity rates, and several are already seeing major spikes in case numbers. Second Reingold Decl. ¶ 41; *see also* Mem. Op. 77 (noting rising infection rates in Oklahoma, which had cited its "stable [and] low levels" of COVID-19 as reason to deny the preliminary injunction). Defendants' meaningless observation that states "have weathered rising and falling COVID-19 rates, but they continue to move forward," Defs.' Mem. 24, provides neither basis nor direction for any geographic narrowing. And Defendants' complaint that the injunction remains in effect for an "indefinite duration," *id.* at 6, 24, is simply false: it is set to end when Defendants themselves declare an end to the nationwide PHE. Dkt. 92, ¶ 2.

Defendants' reliance on the divided ruling in *CASA de Maryland, Inc. v. Trump* for the proposition that this Court's equitable powers do not encompass practical considerations is unavailing. Defs.' Mem. 23-24 (citing 971 F.3d 220, 262 (4th Cir. 2020)). "Crafting a preliminary injunction is an exercise of discretion and judgment, often dependent as much on the equities of a given case as the substance of the legal issues it presents." *Trump v. Int'l Refugee Assistance Project*, 137 S. Ct. 2080, 2087 (2017) (per curiam). A court balances the equities, including the public interest, and "mold[s] its decree to meet the exigencies of the particular case." *Id.* (quoting Charles Alan Wright et al., 11A Federal Practice and Procedure § 2947, at 115 (3d ed. 2013)); *see also*, *e.g.*, *Hecht Co. v. Bowles*, 321 U.S. 321, 329 (1944) ("mercy and practicality," as well as "[f]lexibility rather than rigidity," characterize the courts' equity powers). *CASA de Maryland* in no way undermines this Court's meticulously justified remedy, tailored to Plaintiffs' nationwide membership, the unique administrative challenges of COVID-19 rates that change on a daily basis, and fairness to vulnerable patients during this "unprecedented global pandemic involving COVID-

19, a highly contagious and life-threatening respiratory disease." Mem. Op. 42, 72-80.

First, the majority's criticism of the nationwide remedy in *CASA de Maryland* was dicta. 971 F.3d at 263 ("[T]he district court compounded its error of granting relief with its choice of remedy"); *id.* at 283 (King, J., dissenting) ("[T]he majority's attack [on nationwide injunctions] is dicta"). The two Fourth Circuit cases on which this Court relied—*Roe v. Department of Defense*, 947 F.3d 207 (4th Cir. 2020), and *Lord & Taylor, LLC v. White Flint, L.P.*, 780 F.3d 211 (4th Cir. 2015)—authorize district courts to "assess the practical difficulties of enforcement of an injunction" and remain good law. Mem. Op. 74-78 (quoting *Lord & Taylor*, 780 F.3d at 217).

Second, the *CASA de Maryland* majority found that the "only plaintiffs to this lawsuit who have standing" were the two individual plaintiffs—not CASA de Maryland, Inc., an organization with members in Maryland, Pennsylvania, Virginia, and Washington, D.C.—and thus reasoned that "a nationwide injunction would be wholly unnecessary," because a much narrower injunction preventing the government from applying the challenged rule just to those two individuals would fully redress their injuries. *Lord & Taylor*, 780 F.3d at 262. Here, by contrast, it is undisputed that Plaintiffs' members practice in all 50 states and D.C., and represent 90 percent of the nation's OB/GYNs. *See* Mem. Op. 73-74. There is nothing in *CASA de Maryland* that undermines a Court's ability to grant full relief to an organization that sues on behalf of its members. *Warth v. Seldin,* 422 U.S. 490 (1975). A preliminary injunction that applies nationwide during this nationwide PHE is the only way to provide complete relief to Plaintiffs' members and their patients.

Finally, the *CASA de Maryland* majority criticized the district court's reliance on "pragmatic reasons" because they were based only on the fact that "uniformity is important to immigration law" and contained no "limiting principle." 971 F.3d at 262; *see also CASA de Md., Inc. v. Trump*, 414 F. Supp. 3d 760, 787 (D. Md. 2019)), *rev'd and remanded*, 971 F.3d 220

(district court decision containing one-paragraph analysis on need for "uniform enforcement of immigration laws" rather than "a patchwork of immigration policies applied across the nation"). That non-specific concern for uniformity in immigration law bears no resemblance to this Court's careful analysis of the "practical, administrative complexities" that would impede complete and immediate relief of Plaintiffs' and their members' and patients' injuries in the emergent context of a pandemic. Mem. Op. 76-78. This Court rightly determined that it could not feasibly impose an injunction involving day-to-day checks of the organizational Plaintiffs' members, tethered to constantly fluctuating COVID-19 rates, and that attempting to do so would hamstring the manufacturers, clinicians, and patients subject to the REMS, as well as the FDA itself—and less effectively redress Plaintiffs' injuries. The Court also properly reasoned that the "costs" of attempting to carve out from the unitary, nationwide REMS enforcement scheme the minority of mifepristone prescribers who are not members of the organizational Plaintiffs on the day they prescribe the medication were unwarranted "[w]here an injunction covering Plaintiffs already covers 90 percent of OB/GYN physicians in the United States." *Id.* at 77. Defendants have shown no change in fact since, nor any error, either in equity or in law, in that well-reasoned conclusion.

IV. CONCLUSION

Defendants fall woefully short of proving that circumstances have changed such that the preliminary injunction should be stayed, narrowed, or dissolved. For the foregoing reasons, the motion should be denied.

Dated: November 13, 2020

Respectfully submitted,

/s/ Julia Kaye

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CERTIFICATE OF SERVICE

I hereby certify that this document will be served on the Defendants in accordance with Fed. R. Civ. P. 5.

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