No. 20A34

IN THE SUPREME COURT OF THE UNITED STATES

UNITED STATES FOOD AND DRUG ADMINISTRATION, ET AL., APPLICANTS

v.

AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS, ET AL.

SUPPLEMENTAL BRIEF IN SUPPORT OF APPLICATION FOR A STAY

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On July 13, 2020, the United States District Court for the District of Maryland entered a nationwide preliminary injunction barring the Food and Drug Administration (FDA) from enforcing longstanding safety requirements with respect to medication abortions effected through the use of Mifeprex (or its generic equivalent). See Appl. App. 1a-84a. On August 26, 2020, after the district court and court of appeals had denied the government's motions to stay that nationwide injunction pending appeal, the government filed with this Court an application for a stay of the injunction. This Court subsequently entered an order "hold[ing] the Government's application in abeyance to permit the District Court to promptly consider a motion by the Government to dissolve, modify, or stay the injunction." 10/8/20 Sup. Ct. Order 1.

The additional district-court proceedings contemplated by this Court's Order have now ended, and they confirm that the Court should grant the government's still-pending application for a

stay. The district court adhered to its view that a nationwide preliminary injunction is warranted, see Suppl. App., infra, 1a-36a, despite newly available evidence showing that in States where requirements of in-person visits have remained in effect as a matter of state law, the number of abortions provided during the pandemic has in fact increased as compared to the equivalent period in 2019. See id. at 27a. That data reinforces what the government's earlier filings explained: continued enforcement of FDA's two-decade-old safety requirement during the pandemic does not create a substantial burden on abortion access, and is thus constitutional under the framework established in Planned Parenthood of Se. Pa. v. Casey, 505 U.S. 833 (1992). See Appl. 12-26; Reply Appl. 3-11. The evidentiary proceedings this Court requested have made the district court's earlier error especially stark, and highlight the continuing need for relief from this Court.

ARGUMENT

1. In its application and reply, the government explained that all of the traditional considerations warranting a stay pending further proceedings are readily satisfied here. See Appl. 9-33; Reply Appl. 2-15.

Most importantly, the injunction rests on multiple legal errors. It ignores the fact that the challenged safety requirements impose no obstacle whatsoever to other "commonly used

and generally accepted method[s]" of abortion, and thus cannot be said to "construct a substantial obstacle to the abortion right." Gonzales v. Carhart, 550 U.S. 124, 165 (2007). It flouts this Court's admonition that a law's "incidental effect of making it more difficult or more expensive to procure an abortion cannot be enough to invalidate" the law if the law "serves a valid purpose, one not designed to strike at the right itself." Planned Parenthood of Se. Pa. v. Casey, 505 U.S. 833, 874 (1992) (plurality opinion). And it resuscitates the free-wheeling burdens-and-benefits "balancing test" that five members of this Court rejected just last Term. Appl. App. 37a. Moreover, it does all of that on a nationwide basis untethered from injuries to the plaintiffs (or their members) in this case, and thus from the specific case or controversy that the district court holds "[t]he judicial Power" to resolve. U.S. Const. Art. III, § 2, cl. 1.

The district court's preliminary injunction is preventing FDA from enforcing important, longstanding safety requirements that were adopted in 2000 and that, "[o]ver the course of four presidential administrations, the FDA * * * has not found it appropriate to remove." 10/8/20 Sup. Ct. Order 4 (Alito, J., dissenting). A stay of the district court's nationwide preliminary injunction therefore would have been warranted even without the additional proceedings following this Court's abeyance Order.

2. The additional proceedings make it even clearer that a stay is appropriate. Although the district court discussed at length the many ways in which the COVID-19 pandemic continues to disrupt daily life and threaten public health, see Suppl. App., infra, 15a-27a, it gave short shrift to the only evidence that speaks directly to the crucial issue before it -- whether in-person dispensing requirements would create a substantial burden with respect to abortion access specifically. Fairly considered, the newly available evidence on that issue undermines even further the justifications for the district court's injunction.

Although the district court's injunction has barred FDA from enforcing its in-person dispensing requirement since July, some States independently require an in-person visit in connection with medication abortions. See Suppl. App., infra, 27a (acknowledging that in "Indiana and Nebraska, * * * state law requires an in-person examination before any medication abortion"). Those state-law requirements have remained in effect throughout the pandemic. See ibid. (recognizing that "the Preliminary Injunction has no practical effect in light of state laws" in Indiana and Nebraska). Accordingly, the experiences in Indiana and Nebraska provide a real-world test of the district court's speculation that requiring in-person visits during the pandemic would pose a substantial obstacle to women's access to abortion.

As even the district court recognized, the data from those States does not line up with its predictions from July. See Suppl. App., infra, 27a. In Nebraska, the number of abortions performed between March and September 2020 was 17.5% higher than in the same period a year earlier, notwithstanding that Nebraska "has not suspended [the in-person dispensing] requirement at any point during the COVID-19 pandemic." D. Ct. Doc. 141-6, ¶ 14 (Oct. 30, 2020); see id. ¶ 13. Similarly in Indiana, the number of abortions performed between March and September 2020 was 3.7% higher than in the same period a year earlier. See D. Ct. Doc. 141-7, ¶ 16 & Tbl. (Oct. 30, 2020). The actual data about the effects of in-person dispensing requirements thus undermines, rather than supports, the core premise of the district court's preliminary injunction -- i.e., that requiring in-person visits as part of providing an abortion would substantially impede women's access to abortion during the pandemic.

3. The district court acknowledged that "this data may support [the government's] argument," but declared the data "too incomplete to allow for definitive conclusions." Suppl. App., infra, 27a. In particular, the court noted that 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." Ibid. But that is a reason why this evidence is especially probative: in places where in-person dispensing requirements remain in effect,

there appeared to be no barrier to abortion of the sort that respondents have theorized. And the unavailability of additional data on this point is due in part to the court's own preliminary injunction, which eliminated the in-person dispensing requirements in other States that had previously counted on FDA's requirement to ensure patient safety.

The district court also discounted the available data because that data "does not account for whether * * * the demand for abortions has increased during the COVID-19 pandemic." Suppl. App., infra, 28a. But the only "evidence" of such a possible increase in demand that the court identified, ibid., was a single paragraph of a declaration in which one of the organizational respondents' members opined in general terms that "some people for whom a pregnancy would otherwise have been welcome now feel unable to have a baby at this time" and "many people are having trouble maintaining their contraceptive care." D. Ct. Doc. 11-3, ¶ 20 (May 27, 2020). The court pointed to no actual data supporting that speculation, and respondents made no attempt to introduce evidence establishing, for example, that the preliminary injunction has caused the number of abortions to increase by an even larger proportion in the rest of the country than in Indiana and Nebraska.

Finally, the district court concluded that the data from Indiana and Nebraska "is countered by" a declaration from

respondent Dr. MacNaughton that "describe[ed] multiple examples of actual patients" who "face[d] significant barriers to fulfilling the In-Person Requirements yet were able to obtain a medication abortion" under the injunction. Suppl. App., infra, 28a. But the four anecdotes Dr. MacNaughton offered, see D. Ct. Doc. 142-3, ¶¶ 5, 6, 8, 9 (Nov. 13, 2020), do not begin to counter-balance the state-wide data reflecting thousands of abortions performed in Indiana and Nebraska notwithstanding continued adherence to in-person requirements. Indeed, while Dr. MacNaughton indicated that for those four women, "[b]eing able to obtain their abortion medications at home * * * has been a huge relief," id. ¶ 4, she did not indicate that any of them would have been unable to come for an in-person visit had such a visit been required.

In short, in the additional proceedings requested by this Court, the only non-anecdotal evidence specific to the abortion context provides a further reason to reject the district court's view that enforcing FDA's longstanding in-person dispensing requirement would likely impose a "substantial burden" on abortion access.

CONCLUSION

For the reasons given in the government's August 26, 2020 stay application and September 10 reply, as well as this supplemental brief, the Court should stay the district court's injunction pending the completion of further proceedings in the

court of appeals and, if necessary, this Court. At a minimum, this Court should stay the nationwide scope of the injunction.

Respectfully submitted.

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DECEMBER 2020