

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK**

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TANYA ASAPANSA-JOHNSON WALKER and

CECILIA GENTILI

Plaintiffs,

Civil Action No.
20-CV-02834 (FB) (SMG)

v.

ALEX M. AZAR II, in his official capacity as the
Secretary of the United States Department of Health
and Human Services, and

UNITED STATES DEPARTMENT OF HEALTH
AND HUMAN SERVICES,

Defendants.

-----x

**DEFENDANTS' MEMORANDUM OF LAW IN OPPOSITION TO
PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION**

Date of Service: July 31, 2020

TABLE OF CONTENTS

PRELIMINARY STATEMENT 1

STATEMENT OF FACTS 2

 A. HHS’s 2016 Rule 3

 B. Development of the Challenged Rule 4

 C. The 2020 Rule 5

ARGUMENT 6

I. PLAINTIFFS LACK STANDING 7

 A. Plaintiffs Fail to Show That They are Likely to Suffer Injury in Fact. 7

 B. Plaintiffs Cannot Show that the Government Caused their Alleged
 Injuries or that a Decision by this Court Will Redress Them. 11

II. PLAINTIFFS ARE UNLIKELY TO PREVAIL ON THE MERITS 13

 A. HHS’s Decision Not to Define “On the Basis of Sex” Is Lawful. 14

 B. The 2020 Rule is Not Arbitrary & Capricious 17

 C. The 2020 Rule is Constitutional 20

III. PLAINTIFFS HAVE NOT DEMONSTRATED IRREPARABLE HARM 24

IV. THE BALANCE OF THE EQUITIES & THE PUBLIC INTEREST FAVOR
 DEFENDANTS 28

V. NATIONWIDE RELIEF IS INAPPROPRIATE 29

CONCLUSION 31

TABLE OF AUTHORITIES

CASES

Aetna Life Ins. Co. v. Haworth,
300 U.S. 227 (1937)..... 7

Affinity Healthcare Servs., Inc. v. Sebelius,
720 F. Supp. 2d 12 (D.D.C. 2010)..... 30

Air Transp. Ass’n v. FAA,
169 F.3d 1 (D.C. Cir. 1999)..... 20

Alexander v. Sandoval,
532 U.S. 275 (2001)..... 26

Am. Civil Liberties Union v. Clapper,
804 F.3d 617 (2d Cir. 2015) 14

Ariz. Christian Sch. Tuition Org. v. Winn,
563 U.S. 125 (2011)..... 13

Ashcroft v. Iqbal,
556 U.S. 662 (2009)..... 23

Bellion Spirits, LLC v. United States,
335 F. Supp. 3d 32 (D.D.C. 2018)..... 22

Bostock v. Clayton County,
140 S. Ct. 1731 (2020)..... 15, 16, 18, 23

Branton v. FCC,
993 F.2d 906 (D.C. Cir. 1993)..... 11

Butler v. Obama,
814 F. Supp. 2d 230 (E.D.N.Y. 2011) 11, 13

California v. Yamasaki,
442 U.S. 682 (1979)..... 29

California by & through Becerra v. Azar,
950 F.3d 1067 (9th Cir. 2020) 17

Camp v. Pitts,
411 U.S. 138 (1973)..... 22

Chiayu Chang v. USCIS.,
254 F. Supp. 3d 160 (D.D.C. 2017)..... 22

Chunn v. Edge,
 -- F. Supp. 3d. -- , 2020 WL 3055669 (E.D.N.Y. June 9, 2020) 14

City of Los Angeles v. Lyons,
 461 U.S. 95 (1983)..... 9, 24

Clapper v. Amnesty Int’l USA,
 568 U.S. 398 (2013)..... 8, 27

Coal. for Econ. Equity v. Wilson,
 122 F.3d 692 (9th Cir. 1997), *dismissing stay*, 122 F.3d 718 (9th Cir. 1997)..... 21

Connecticut v. Massachusetts,
 282 U.S. 660 (1931)..... 25

Cooling Water Intake Structure Coal v. U.S. Env’tl. Protection Agency,
 905 F.3d 49 (2d Cir. 2018) 17

Cooper Hosp./Univ. Med. Ctr. v. Burwell,
 179 F. Supp. 3d 31 (D.D.C. 2016)..... 23

Cooper v. U.S. Postal Serv.,
 577 F.3d 479 (2d Cir. 2009) 7

Cty. of Westchester v. U.S. Dept. of Hous. and Urb. Dev.,
 802 F.3d 413 (2d Cir. 2015) 14

Dep’t of Commerce v. New York,
 139 S. Ct. 2551 (2019), *remanded*, 2019 WL 3213840 (S.D.N.Y. July 16, 2019) 22, 23

DHS v. New York,
 140 S. Ct. 599 (2020), *denying modification*, 2020 WL 1969276 (U.S. Apr. 24, 2020)..... 29

Evancho v. Pine-Richland Sch. Dist.,
 237 F. Supp. 3d 267 (W.D. Pa. 2017)..... 27

Faiveley Transp. Malmo AB v. Wabtec Corp.,
 559 F.3d 110 (2d Cir. 2009) 24

FCC v. Fox Television Stations, Inc.,
 556 U.S. 502 (2009)..... 19, 20

Fla. Bankers Ass’n v. U.S. Dep’t of Treas.,
 19 F. Supp. 3d 111 (D.D.C. 2014), *vacated on other grounds*,
 799 F.3d 1065 (D.C. Cir. 2015)..... 20

Franciscan All. Inc. v. Azar,
 414 F. Supp. 3d 928 (N.D. Tex. 2019), *filing appeal*,
 No. 20-10093 (5th Cir. Jan. 24, 2019)..... *passim*

Franciscan All. Inc. v. Burwell,
227 F. Supp. 3d 660 (N.D. Tex. 2016) 4

Friends of Animals v. Romero,
948 F.3d 579 (2d Cir. 2020) 20

Gill v. Whitford,
138 S. Ct. 1916 (2018)..... 29

Grand River Enter. Six Nations, Ltd. v. Pryor,
481 F.3d 60 (2d Cir. 2007) 24

Guertin v. United States,
743 F.3d 382 (2d Cir. 2014) 14

Harvard Pilgrim Health Care of New England v. Thompson,
318 F. Supp. 2d 1 (D.R.I. 2004) 22

Jarita Mesa Livestock Grazing Ass’n v. U.S. Forest Serv.,
58 F. Supp. 3d 1191 (D.N.M. 2014)..... 22

Kaplan v. Bd. of Educ. of City Sch. Dist. of City of N.Y.,
759 F.2d 256 (2d Cir. 1985) 25

Karpova v. Snow,
497 F.3d 262 (2d Cir. 2007) 14

Ketcham v. U.S. Nat’l Park Serv.,
Case No. 16-CV-00017-SWS, 2016 WL 4268346 (D. Wyo. Mar. 29, 2016)..... 22

Linda R.S. v. Richard D.,
410 U.S. 614 (1973)..... 12

Lopez v. City of New York,
2009 WL 229956 (S.D.N.Y. Jan. 30, 2009) 21

Lujan v. Defs. of Wildlife,
504 U.S. 555 (1992)..... *passim*

Madsen v. Women’s Health Ctr., Inc.,
512 U.S. 753 (1994)..... 29

Maryland v. King,
567 U.S. 1301 (2012)..... 28

Masterpiece Cakeshop, Ltd. v. Colo. Civil Rights Comm’n,
138 S. Ct. 1719 (2018)..... 23

MD/DC/DE Broads. Ass’n v. FCC,
236 F.3d 13 (D.C. Cir. 2001)..... 30

MGM Resorts Intl. Glob. Gaming Dev., LLC v. Malloy,
861 F.3d 40 (2d Cir. 2017), *as amended* (Aug. 2, 2017)..... 10

Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto. Ins. Co.,
463 U.S. 29 (1983)..... 14

N.Y. Progress & Prot. PAC v. Walsh,
733 F.3d 483 (2d Cir. 2013) 14

N.Y. State Nat. Org. for Women v. Terry,
886 F.2d 1339 (2d Cir. 1989) 25

Nken v. Holder,
556 U.S. 418 (2009)..... 14, 28

Printz v. United States,
521 U.S. 898 (1997)..... 31

Raia v. Pompeo,
-- F. Supp. 3d -- , 2020 WL 1921573 (E.D.N.Y. Apr. 21, 2020) 24, 25

Regents of the Univ. of Cal.,
140 S. Ct. 1891 (2020)..... 22

Romer v. Evans,
517 U.S. 620 (1996)..... 24

Schweiker v. Wilson,
450 U.S. 221 (1981)..... 21

Shain v. Ellison,
356 F.3d 211 (2d Cir. 2004) 26

Sierra Club v. Morton,
405 U.S. 727 (1972)..... 8

Simon v. E. Ky. Welfare Rights Org.,
426 U.S. 26 (1976)..... 11, 12, 13

Spokeo, Inc. v. Robins,
136 S. Ct. 1540 (2016)..... 8

St. Francis Med. Ctr. v. Azar,
894 F.3d 290 (D.C. Cir. 2018)..... 16

Tafas v. Dudas,
530 F. Supp. 2d 786 (E.D. Va. 2008) 22

Trump v. Hawaii,
138 S. Ct. 2392 (2018), *remanded*, 898 F.3d 1266 (9th Cir. 2018)..... 29, 30

Univ. of Tex. v. Camenisch,
451 U.S. 390 (1981)..... 29

Weaver’s Cove Energy, LLC v. R.I. Dep’t of Env’tl. Mgmt.,
524 F.3d 1330 (D.C. Cir. 2008)..... 12

Whitaker by Whitaker v. Kenosha Unified Sch. Dist. No. 1 Bd. of Educ.,
858 F.3d 1034 (7th Cir. 2017), *cert. dismissed*, 138 S. Ct. 1260 (2018)..... 21, 27

White v. City of New York,
206 F. Supp. 3d 920 (S.D.N.Y. 2016) 21

Whitmore v. Arkansas,
495 U.S. 149 (1990)..... 8

Windsor v. United States,
699 F.3d 169 (2d Cir. 2012) 21

Winter v. NRDC,
555 U.S. 7 (2008)..... 14, 24, 31

Wis. Gas Co. v. FERC,
758 F.2d 669 (D.C. Cir. 1985)..... 25

Wyeth v. Levine,
555 U.S. 555 (2009)..... 16

STATUTES

5 U.S.C. § 705..... 30

5 U.S.C. § 706..... 14, 17

20 U.S.C. § 1681 *et seq.*..... 3

20 U.S.C § 1681 3, 15, 16

20 U.S.C § 1688..... 3

29 U.S.C. § 794..... 3

42 U.S.C. § 2000d *et seq.*..... 3

42 U.S.C § 2000e-2..... 16

42 U.S.C. § 6101 *et seq.*..... 3

42 U.S.C § 18114..... 17

42 U.S.C. § 18116..... 3, 13, 16

Affordable Care Act,
 Pub. L. No. 111–148, 124 Stat. 119 (2010) 1

REGULATIONS

10 NYCRR § 405.7..... 9
 11 NYCRR § 52.75 (effective July 28, 2020) 9
 45 C.F.R. Part 92..... 3
 45 C.F.R. § 92.3 30
 45 C.F.R. § 92.5 6
 45 C.F.R. § 92.6 6
 45 C.F.R. § 92.207 4
 45 C.F.R. § 92.302 26

Nondiscrimination in Health Programs and Activities,
 81 Fed. Reg. 31,375 (May 18, 2016) *passim*

Nondiscrimination in Health & Health Educ. Programs or Activities,
 84 Fed. Reg. 27,846 (June 14, 2019) 5, 28

Nondiscrimination in Health & Health Educ. Programs or Activities, Delegation
 of Authority,
 85 Fed. Reg. 37,160 (June 19, 2020) *passim*

OTHER AUTHORITIES

Hillsdale College, “Scholarships & Financial Aid-Quality Education Affordable Cost”,
<https://www.hillsdale.edu/admissions-aid/financial-aid/> 13

N.Y. Dep’t of Fin. Servs., Ins. Circular Letter No. 13 (Jun. 28, 2020),
https://www.dfs.ny.gov/industry_guidance/circular_letters/cl2020_13 10

PRELIMINARY STATEMENT

On June 19, 2020, the Department of Health and Human Services (“HHS”) published a rule designed to enforce nondiscrimination provisions in healthcare and to remove regulatory burdens (the “2020 Rule,” “Final Rule,” or “Rule”). The Rule hews closely to the underlying text of Section 1557 of the Affordable Care Act (“ACA”), Pub. L. No. 111–148, 124 Stat. 119 (2010) (“section 1557”), which incorporates protections from other statutes, namely, Title VI of the Civil Rights Act of 1964, Title IX of the Education Amendments Act of 1972, the Age Discrimination Act of 1975, and Section 504 of the Rehabilitation Act of 1973. In 2016, a prior iteration of the Rule (the “2016 Rule”) had attempted to impose a number of requirements not compelled by the ACA. But a court enjoined the 2016 Rule and ultimately vacated “gender identity” from its definition of “on the basis of sex.”

Plaintiffs bring this suit seeking vacatur of the 2020 Rule as well as a nationwide injunction prohibiting its enforcement, arguing that HHS should reissue an expanded version of the very provision that was vacated from the 2016 Rule. But plaintiffs, two individuals who reside in New York City and thus already receive all of the legal protections they desire under state and local law, cannot explain how the 2020 Rule injures them—or even how any alleged harm would be caused by the government rather than by third parties. Because plaintiffs’ allegations do not establish standing, this Court need not reach the merits of their challenge.

But even if this Court had jurisdiction to entertain plaintiffs’ claims—that the 2020 Rule is unlawful, exceeded HHS’s statutory authority, is arbitrary and capricious, and violates Fifth Amendment equal protection—plaintiffs fail to establish a likelihood of success on the merits, a necessary showing to support the extraordinary remedy they demand. Because the 2020 Rule tracks the text of Section 1557 with respect to the definition of “on the basis of sex,” plaintiffs cannot show that it is legally invalid. Nor can plaintiffs demonstrate that HHS acted arbitrarily and

capriciously in issuing the Rule, given the thorough reasoning the Agency provided to support its decision. That plaintiffs have a number of policy disagreements with the 2020 Rule is insufficient to support a claim under the Administrative Procedure Act.

Plaintiffs' constitutional claim fares no better. Plaintiffs identify no action that might support an equal-protection claim under the Fifth Amendment. Plaintiffs fail to explain how the Rule, which incorporates the standard contained in Title IX, is discriminatory, and plaintiffs provide no case law establishing that the 2020 Rule is subject to strict scrutiny.

Even if plaintiffs could show that their claims are likely to succeed on the merits, they would still be precluded from receiving a preliminary injunction. That is because the irreparable injury plaintiffs allege is both speculative and amorphous, and it depends entirely on the potential conduct of unnamed third parties not before this Court. Furthermore, plaintiffs cannot justify ignoring the impact an injunction would have on the general public, which would be deprived of the clarity and protection the 2020 Rule provides. If the court were to determine an injunction is warranted, the Rule's severability clause and plaintiffs' sparse showing of injury demonstrate that nearly all of the Rule's text should be allowed to proceed, and with no nationwide injunction.

In sum, plaintiffs have failed to satisfy the exceedingly high threshold that they must meet to enjoin agency action. Their request for a preliminary injunction should be denied.

STATEMENT OF FACTS

This case arises from HHS's efforts to implement Section 1557 of the Affordable Care Act. Section 1557 applies long-standing anti-discrimination principles to health programs or activities by incorporating four federal anti-discrimination laws into the ACA: Title VI, Title IX, the Age Discrimination Act of 1975, and Section 504 of the Rehabilitation Act. Specifically, Section 1557 directs that

[e]xcept as otherwise provided for in this title (or an amendment made by this title),

an individual shall not, on the ground prohibited under title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d et seq.), title IX of the Education Amendments of 1972 (20 U.S.C. 1681 et seq.), the Age Discrimination Act of 1975 (42 U.S.C. 6101 et seq.), or section [504 of the Rehabilitation Act of 1973 (29 U.S.C. 794)], be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance, including credits, subsidies, or contracts of insurance, or under any program or activity that is administered by an Executive Agency or any entity established under [Title I of the ACA] (or amendments). The enforcement mechanisms provided for and available under such title VI, title IX, section [504], or such Age Discrimination Act shall apply for purposes of violations of this subsection.

42 U.S.C. § 18116(a). Section 1557 states that the Secretary of HHS “may” (but not that he must) issue implementing regulations. *Id.* § 18116(c). As relevant here, Title IX in turn provides that “[n]o person . . . shall, on the basis of sex, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any education program or activity receiving Federal financial assistance.” 20 U.S.C. § 1681(a). Title IX states that it does not apply to religious organizations where it would conflict with the religious tenets of such organizations, § 1681(a)(3), and that nothing in it “shall be construed to require or prohibit any person, or public or private entity, to provide or pay for any benefit or service, including the use of facilities, related to an abortion,” *id.* § 1688.

A. HHS’s 2016 Rule

Acting under its statutory authority to “promulgate regulations to implement” Section 1557, 42 U.S.C. § 18116(c), HHS issued a rule in May 2016, codified at 45 C.F.R. Part 92 (“the 2016 Rule”). *See* Nondiscrimination in Health Programs and Activities, 81 Fed. Reg. 31,375 (May 18, 2016). The 2016 Rule included many provisions implementing Section 1557. As relevant here, the 2016 Rule prohibited discrimination on the basis of sex, and explicitly defined “[o]n the basis of sex” to include “discrimination on the basis of pregnancy, false pregnancy, termination of pregnancy, or recovery therefrom, childbirth or related medical conditions, sex stereotyping, and

gender identity.” *Id.* at 31,467. The 2016 Rule further defined “gender identity” to include “an individual’s internal sense of gender, which may be male, female, neither, or a combination of male and female” *Id.* The 2016 Rule listed several specific examples of prohibited discrimination. *See, e.g., id.* at 31,471 (codified at 45 C.F.R. § 92.207). HHS had decided, for example, that covered entities violate Section 1557 if they “deny or limit coverage of a claim, or impose additional cost sharing or other limitations or restrictions on coverage, for specific health services related to gender transition if such denial, limitation, or restriction results in discrimination against a transgender individual.” *Id.* at 31,472 (codified at 45 C.F.R. § 92.207(b)(5)). In addition to delineating some examples of what violated Section 1557, the 2016 Rule included a catchall provision providing that “[t]he enumeration of specific forms of discrimination . . . does not limit the general applicability of the prohibition” against covered discrimination. *Id.* (codified at 45 C.F.R. § 92.207(c)).

B. Development of the Challenged Rule

In December 2016, the United States District Court for the Northern District of Texas preliminarily enjoined enforcement of parts of the 2016 Rule on a nationwide basis, *Franciscan All. Inc. v. Burwell*, 227 F. Supp. 3d 660, 696 (N.D. Tex. 2016); in May 2017, HHS moved to voluntarily remand that rule so that HHS could “assess the reasonableness, necessity, and efficacy” of the enjoined provisions, *Franciscan All. v. Price*, No. 7:16-cv-00108, ECF No. 92 (N.D. Tex. May 2, 2017); and in October 2019, the court vacated the rule’s definition of “on the basis of sex” insofar as the definition included “gender identity” and “termination of pregnancy,” *Franciscan All. Inc. v. Azar*, 414 F. Supp. 3d 928, 946–47 (N.D. Tex. 2019), *filing appeal*, No. 20-10093 (5th Cir. Jan. 24, 2020), *Franciscan Alliance v. Azar*, No. 7:16-cv-00108, ECF No. 182 (N.D. Tex. Nov. 21, 2019). In June 2019, HHS published a Proposed Rule, which sought “to make substantial revisions to the Section 1557 Regulation and to eliminate provisions that are inconsistent or

redundant with pre-existing civil rights statutes and regulations prohibiting discrimination on the basis of race, color, national origin, sex, age, and disability.” Nondiscrimination in Health and Health Educ. Programs or Activities, 84 Fed. Reg. 27,846, 27,848–49 (June 14, 2019). In so doing, the agency also proposed retaining significant aspects of the 2016 Rule. *Id.* at 27,849. The Proposed Rule would “empower [HHS] to continue its robust enforcement of civil rights laws prohibiting discrimination on the basis of race, color, national origin, sex, age, or disability in [HHS]-funded health programs or activities, and would make it clear that such civil rights laws remain in full force and effect.” *Id.*

C. The 2020 Rule

HHS received nearly 200,000 comments on the Proposed Rule. After carefully evaluating the extensive record, HHS published the Final Rule one year later on June 19, 2020. Nondiscrimination in Health & Health Educ. Programs or Activities, Delegation of Authority, 85 Fed. Reg. 37,160, 37,160. Consistent with the Proposed Rule, the Final Rule makes several revisions to the Section 1557 regulations, ensuring robust protection of civil rights under the statute.

Most relevant here, rather than adopt new definitions for existing civil rights statutes, the 2020 Rule follows the approach of Section 1557 itself by simply incorporating those underlying statutes and regulations in large part. It thus “repeals the 2016 Rule’s definition of ‘on the basis of sex,’ [and] declines to replace it with a new regulatory definition.” *Id.* at 37,178. It also eliminates the gender identity provisions from the 2016 Rule, acknowledging that the decision in *Franciscan Alliance* foreclosed their inclusion. *See, e.g., id.* at 37,164–65. HHS further explained, in the rule’s preamble but not the regulatory text, that, while “the 2016 Rule required covered entities to ‘treat individuals consistent with their gender identity’ in virtually every respect,” *id.* at 37,189, “certain single-sex medical procedures, treatments, or specializations are rooted” in a patient’s biological

sex, *id.* at 37,187, and “reasonable distinctions on the basis of sex” may sometimes be permissible “in the field of health services,” *id.* at 37,185. Accordingly, HHS “repeal[ed] a mandate that was, at least, ambiguous and confusing.” *Id.* at 37,187.

HHS made clear, however, that regardless of its views, the inclusion of “gender identity” in the definition of “on the basis of sex” had already been vacated from the 2016 Rule, and that the Final Rule did nothing more than ensure that the Section 1557 regulations “conform to the plain meaning of the underlying civil rights statutes.” *Id.* at 37,161; *see id.* at 37,180. Because the 2020 Rule merely replaces the 2016 Rule’s explicit definition of “on the basis of sex” by hewing to the text of Section 1557, “to the extent that a Supreme Court decision is applicable in interpreting the meaning of a statutory term, the elimination of a regulatory definition of such term would not preclude application of the Court’s construction.” *Id.* at 37,168.

The 2020 Rule also made several additional changes to the 2016 Rule not challenged by plaintiffs. For example, it modified the 2016 Rule’s enforcement mechanisms to instead apply “the enforcement mechanisms provided for, and available under” the statutes incorporated by reference into Section 1557 “with their respective implementing regulations.” *Id.* at 37,202; *id.* at 37,245 (to be codified at 45 C.F.R. § 92.5). The 2020 Rule “modifies the 2016 Rule’s definition of entities covered by Section 1557,” *id.* at 37,162, and it also “eliminates . . . burdensome requirement[s]” governing consumer notices, *id.* at 37,162. Finally, the 2020 Rule explicitly clarifies that the application of Section 1557’s requirements “shall not be imposed or required” if doing so would conflict with certain statutes, including certain laws protecting conscience and religious liberty. *Id.* at 37,245 (to be codified at 45 C.F.R. § 92.6(b)).

ARGUMENT

The 2020 Rule represents a valid exercise of HHS’s authority to enact regulations implementing Section 1557’s prohibition on discrimination. In issuing the Rule, HHS remained

faithful to the statute’s text—indeed, the provision of the 2020 Rule plaintiffs challenge simply defers to the underlying statute. Yet plaintiffs demand more. They argue that the statute itself was not enough—that HHS should have taken upon itself the duty to define “on the basis of sex,” and should have done so in a manner even more expansive than the vacated 2016 Rule attempted. Plaintiffs, who unquestionably have strong policy disagreements with the 2020 Rule, provide no legal argument to support their claim that it is invalid. Their demand that this Court take the extraordinary measure of enjoining the Rule before it goes into effect should be rejected.¹

I. PLAINTIFFS LACK STANDING

To bring a challenge, a plaintiff bears the burden of showing that it suffers “injury in fact” that is “fairly . . . trace[able]” to a defendant’s conduct and that will “be redressed by a favorable decision.” *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560–61 (1992) (citation omitted); *Cooper v. U.S. Postal Serv.*, 577 F.3d 479, 489 (2d Cir. 2009). Plaintiffs in this case, who cannot identify a concrete harm caused by the government—let alone one that this Court is capable of redressing—fail to demonstrate that they have Article III standing.

A. Plaintiffs Fail to Show That They Are Likely to Suffer an Injury in Fact.

To invoke federal subject-matter jurisdiction, a party must establish the existence of a “justiciable controversy” with the adverse party—one that is “definite and concrete, touching the legal relations of parties having adverse legal interests.” *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 240–41 (1937). A plaintiff must have suffered an “injury-in-fact,” meaning “an invasion of a legally protected interest which is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical.” *Lujan*, 504 U.S. at 560 & n.1 (internal quotation marks and citations

¹ Although plaintiffs make passing references to other provisions in the 2020 Rule, their legal arguments are directed exclusively at HHS’s decision not to include a definition for “on the basis of sex.” Defendants accordingly limit their arguments to defending that aspect of the Rule.

omitted); *see also Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547–48 (2016); *Sierra Club v. Morton*, 405 U.S. 727, 740–41 n.16 (1972). If the injury has not already occurred, plaintiffs must demonstrate that it is “certainly impending.” *Clapper v. Amnesty Int’l USA*, 568 U.S. 398, 401 (2013) (quoting *Whitmore v. Arkansas*, 495 U.S. 149, 158 (1990)).

While plaintiffs’ complaint, motion, and declarations are filled with speculation as to what they claim will happen in the wake of the 2020 Rule, plaintiffs cannot show that they are likely to suffer actual harm. *See Lujan*, 504 U.S. at 560–61. Plaintiffs allege that the Rule “threatens Plaintiffs’ ability to access and receive adequate health care,” Mem. in Supp. of Pls.’ Expedited Mot. for Prelim. Inj., at 3, ECF No. 8-1 (“Mot.”), but they fail to show how such an injury would result.

First, plaintiffs lack standing to challenge any aspect of the 2020 Rule for the fundamental reason that the harm plaintiffs allege is conjectural. The mere threat of potential future harm is insufficient to establish standing; instead, plaintiffs must identify an injury that is “certainly impending.” *Clapper*, 568 U.S. at 401 (quoting *Whitmore*, 495 U.S. at 158). Plaintiffs come nowhere close to satisfying that standard. Instead, plaintiffs claim to fear actions third parties *may* take as a result of the Rule. Specifically, plaintiffs predict that the 2020 Rule will “expose[] them to discriminatory, verbally abusive treatment, sub-standard care, or a denial of coverage for medical treatments just by virtue of their sexual orientation and/or gender identity.” Mot. at 12. But such an outcome is not inevitable—far from it. It is no wonder, then, that plaintiffs cannot identify which providers are likely to engage in such conduct, or which plaintiff may be harmed as a result—the injury alleged is wholly speculative and therefore insufficient to support Article III standing. *See Lujan*, 504 U.S. at 560.

Indeed, plaintiffs’ predictions are predicated almost entirely on past events. After recounting a history of what plaintiffs describe as discriminatory conduct, plaintiffs conclude that

“[t]his past reveals a future threat.” Mot. at 13; *see* Compl. ¶ 17 (“Health care professionals and staff have discriminated against Plaintiffs prior to and after the promulgation of the 2016 Rule, and Plaintiffs fear that the 2020 Rule will only increase the likelihood that they will experience this discrimination again.”). But “[p]ast exposure to illegal conduct does not in itself show a present case or controversy regarding injunctive relief . . . if unaccompanied by any continuing, present adverse effects.” *City of Los Angeles v. Lyons*, 461 U.S. 95, 102 (1983) (citation omitted). Plaintiffs’ alleged past harms were not caused by the 2020 Rule, which has yet to take effect. Plaintiffs cannot explain why these past harms are now imminent, let alone how the 2020 Rule will cause them.

Second, even if plaintiffs could show that the 2020 Rule may injure some individuals, it is clear that the Rule will have zero impact on *plaintiffs*. It is uncontested that both plaintiffs are residents of New York City. *See* Compl. ¶¶ 21–22. New York law, which the 2020 Rule does not preempt, already provides all of the protections plaintiffs desire. *See* 85 Fed. Reg. at 37,182, 37,199 & n.236; Decl. of Tanya Asapansa-Johnson Walker ¶ 6, ECF No. 1-2 (“Walker Decl.”) (describing successful efforts at adding “gender identity or expression” to the New York State Human Rights Law). For example, the New York Department of Health explicitly prohibits healthcare providers from discriminating on the basis of gender identity. *See* 10 NYCRR § 405.7(b)(2) (“hospital shall afford to each patient the right to treatment without discrimination as to race, color, religion, sex, gender identity, national origin, disability, sexual orientation, age or source of payment”). Likewise, the New York State Department of Financial Services forbids insurers from discriminating on the basis of sex, and provides that “[d]iscrimination because of sex shall include discrimination on the basis of pregnancy, false pregnancy, termination of pregnancy, or recovery therefrom, childbirth or related medical conditions, sex stereotyping, sexual orientation, gender identity or expression, and transgender status.” 11 NYCRR § 52.75(b)(2) (effective July 28, 2020).

Indeed, New York has taken action *specifically in response to the 2020 Rule*. See N.Y. Dep’t of Fin. Servs., Ins. Circular Letter No. 13 (Jun. 28, 2020), https://www.dfs.ny.gov/industry_guidance/circular_letters/cl2020_13 (last visited July 30, 2020). Thus, even had plaintiffs plausibly alleged that the 2020 Rule would lead to the injuries they complain of elsewhere in the United States, the 2020 Rule will have no impact on plaintiffs’ ability to obtain health care in New York.

In apparent recognition of the fact that plaintiffs cannot demonstrate that they will suffer any injury within the State of New York, plaintiff Cecilia Gentili’s declaration includes the following statement: “I have imminent work-related travel planned to California, Texas, Georgia, and Florida. Because of the 2020 Rule, I am petrified to make these trips out of fear of how I would be treated were I to require health care for any reason.” Decl. of Cecilia Gentili ¶ 65, ECF No. 1-3 (“Gentili Decl.”).² Simply using the word “imminent,” however, is not enough to demonstrate concrete harm. As the Supreme Court has made clear, a mere intention to visit a location “without any description of concrete plans, or indeed even any specification of *when* the” plaintiff intends to make a visit, “do not support a finding of the ‘actual or imminent’ injury that our cases require.” *Lujan*, 504 U.S. at 564 (citation omitted); cf. *MGM Resorts Intl. Glob. Gaming Dev., LLC v. Malloy*, 861 F.3d 40, 47 (2d Cir. 2017), *as amended* (Aug. 2, 2017) (explaining that a casino developer lacked standing to challenge Connecticut law because it had “not alleged any concrete plans to enter into a development agreement with a Connecticut municipality”). Plaintiff Gentili has not provided any information regarding when the alleged travel may occur, how long its duration will be, or even what, exactly, the destinations will be beyond a list of four states. Indeed, despite referencing “imminent” travel, the declaration acknowledges that travel will not occur until

² Plaintiff Walker does not allege any plans to travel out of state.

it “becomes safe again”—an uncertain timeline, to say the least. Gentili Decl. ¶ 64. And the declaration only speculates that Plaintiff Gentili would require medical care on such trips—let alone that a healthcare provider would discriminate. Plaintiff Gentili’s statement thus falls far short of establishing imminent concrete harm. *See Butler v. Obama*, 814 F. Supp. 2d 230, 234–35 (E.D.N.Y. 2011) (Bianco, J.) (finding no standing to challenge ACA’s individual mandate provision based on speculative harm).

B. Plaintiffs Cannot Show that the Government Caused Their Alleged Injuries or that a Decision by this Court Will Redress Them.

In addition to establishing injury in fact, a plaintiff must demonstrate a connection between the defendant, the conduct alleged, and the remedy sought. Specifically, a plaintiff must show that the defendant’s conduct—rather than that of a third party—caused the injuries alleged, and that a decision in the plaintiff’s favor will redress those injuries. *See Lujan*, 504 U.S. at 560–61. Plaintiffs can do neither here.

First, plaintiffs cannot demonstrate that the 2020 Rule caused their alleged injuries. To establish standing, “there must be a causal connection between the injury and the conduct complained of—the injury has to be ‘fairly . . . trace[able] to the challenged action of the defendant, and not . . . th[e] result [of] the independent action of some third party not before the court.’” *Lujan*, 504 U.S. at 560 (quoting *Simon*, 426 U.S. at 41–42). In *Simon v. Eastern Kentucky Welfare Rights Organization*, for example, the Supreme Court held that advocacy organizations lacked standing to challenge an IRS regulation they believed would induce hospitals to deny services because “injury at the hands of a hospital is insufficient by itself to establish a case or controversy [where] no hospital is a defendant.” *See* 426 U.S. at 41; *see also Branton v. FCC*, 993 F.2d 906, 910–11 (D.C. Cir. 1993) (“The Supreme Court is particularly disinclined to find that the causation and redressability requirements are satisfied where a complainant challenges only an

Executive Branch decision not to impose costs or penalties upon some third party.”).

Just like in *Simon*, plaintiffs here do not allege that the *government* will injure them by refusing to provide medical services. Instead, plaintiffs claim that the challenged component of the 2020 Rule may lead *healthcare providers* to deny services to certain patients. *See, e.g.*, Mot. at 10 (“[T]he 2020 Rule will cause Plaintiffs irreparable harm by exposing them to discrimination in vital medical treatment.”). To the extent this Rule could be said not to prohibit behavior plaintiffs fear, their dispute would be with healthcare providers who engage in those practices—not with the government. *See Weaver’s Cove Energy, LLC v. R.I. Dep’t of Env’tl. Mgmt.*, 524 F.3d 1330, 1333 (D.C. Cir. 2008) (“A’s injuring B does not create a case or controversy between B and C.” (citing *Linda R.S. v. Richard D.*, 410 U.S. 614, 618 (1973))).

Second, plaintiffs cannot show that any remedy this Court orders would be likely to redress the harm complained of. *See Lujan*, 504 U.S. at 561; *Simon v. E. Ky. Welfare Rights. Org.*, 426 U.S. 26, 41–42 (1976). Plaintiffs argue that HHS should have included additional language in the 2020 Rule that might dissuade healthcare providers from discriminating against them, *see* Mot. at 1; Gentili Decl. ¶ 73–74, but there is no available remedy for achieving that end because the prior inclusion of “gender identity” in the definition of “on the basis of sex” was vacated by another court before this Rule was finalized, *Franciscan All.*, 414 F. Supp. 3d at 947, and the 2016 Rule itself omitted sexual orientation as a prohibited discrimination category. Enjoining the challenged 2020 Rule would leave plaintiffs with the non-vacated portions of the 2016 Rule and Section 1557 itself, neither of which contains the definition of “on the basis of sex” plaintiffs prefer.

Third, even if this Court could order the agency to rewrite the 2020 Rule according to plaintiffs’ specifications, such a result would not redress plaintiffs’ alleged harm. In *Simon*, plaintiffs attempted to make the very same argument that plaintiffs make here—that a particular federal policy might encourage individuals to engage in allegedly objectionable conduct. *Compare*

Simon, 426 U.S. at 42 (“The complaint here alleged only that petitioners, by the adoption of Revenue Ruling 69-545, had ‘encouraged’ hospitals to deny services to indigents.”), *with* Mot. at 13 (alleging that 2020 Rule will “allow[] Plaintiffs to be discriminated against in seeking health care solely on account of their gender identities”). As in *Simon*, a favorable judgment here would not ensure that these third-party providers would cease engaging in the conduct plaintiffs dislike. See *Butler*, 814 F. Supp. 2d at 240 (“In short, plaintiff is simply speculating how insurance companies might react if the Act is struck down as unconstitutional.”). Moreover, it is possible that some providers could choose to avoid Section 1557 altogether by refusing to accept federal funds. See 42 U.S.C. 18116(a) (applying restrictions to “any health program or activity, any part of which is receiving Federal financial assistance”). While foregoing federal funds may not be an attractive option to many, doing so would be far from unprecedented—in other contexts organizations have chosen to do precisely that so as to avoid federal regulation.³

Here, there is no indication that plaintiffs have been impacted by the 2020 Rule in any meaningful way, much less suffered an injury-in-fact sufficient to confer standing to challenge it. Simply put, speculation that a yet-to-be-identified private provider may deny service to a patient at some point in the future is insufficient to establish standing vis-à-vis the government. Because “[e]ach of the inferential steps to show causation and redressability depends on premises as to which there remains considerable doubt,” *Ariz. Christian Sch. Tuition Org. v. Winn*, 563 U.S. 125, 138 (2011), there is no standing to support plaintiffs’ challenge.

II. PLAINTIFFS ARE UNLIKELY TO PREVAIL ON THE MERITS

To obtain a preliminary injunction “a litigant must establish (1) a likelihood of success on

³ For example, Hillsdale College, “[t]o maintain [its] institutional independence, . . . accept[s] no state or federal funding—even indirectly in the form of student grants or loans.” Hillsdale College, “Scholarships & Financial Aid-Quality Education Affordable Cost” <https://www.hillsdale.edu/admissions-aid/financial-aid/> (last visited July 30, 2020).

the merits, (2) a likelihood of irreparable harm in the absence of preliminary relief, (3) that the balance of equities tips in the party's favor, and (4) that an injunction is in the public interest." *Chunn v. Edge*, -- F. Supp. 3d. -- , 2020 WL 3055669, at *23 (E.D.N.Y. June 9, 2020) (citing *Am. Civil Liberties Union v. Clapper*, 804 F.3d 617, 622 (2d Cir. 2015)).

A party must first show that it "is likely to succeed on the merits." *See N.Y. Progress & Prot. PAC v. Walsh*, 733 F.3d 483, 486 (2d Cir. 2013) (quoting *Winter v. NRDC*, 555 U.S. 7, 20 (2008)); *see also Nken v. Holder*, 556 U.S. 418, 434 (2009). Here, that means demonstrating that the 2020 Rule is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). "[T]he scope of review under the 'arbitrary and capricious' standard is narrow,' and courts should not substitute their judgment for that of the agency." *Karpova v. Snow*, 497 F.3d 262, 267 (2d Cir. 2007) (quoting *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)). Plaintiffs come nowhere close to satisfying this "deferential standard of review"—or establishing any other violation of the APA. *Cty. of Westchester v. U.S. Dept. of Hous. and Urb. Dev.*, 802 F.3d 413, 430–31 (2d Cir. 2015) (quoting *Guertin v. United States*, 743 F.3d 382, 385–86 (2d Cir. 2014)).

A. HHS's Decision Not to Define "On the Basis of Sex" Is Lawful.

Rather than providing a definition of "on the basis of sex," the 2020 Rule simply prohibits discrimination on the grounds prohibited by Title IX. Plaintiffs' argument that the 2020 Rule, in so doing, is somehow invalid because it did not include language found nowhere in its authorizing statute is meritless.

Plaintiffs argue that "the Department's 2020 Rule is irreconcilable with how Congress understood the term 'sex' at the time it adopted Section 1557," Mot. at 22, and that the Rule "adopt[s] an interpretation at odds with the plain text of the statute," *id.* at 23. But plaintiffs do not explain *how* the 2020 Rule's strict adherence to the grounds prohibited by Title IX's prohibition

of discrimination “on the basis of sex” runs afoul of Section 1557. Section 1557 does not use the term “sex,” but instead incorporates the prohibition contained in Title IX, which in turn provides: “No person in the United States shall, on the basis of sex, . . . be subjected to discrimination under any education program or activity receiving Federal financial assistance” 20 U.S.C. § 1681(a). By declining to include a definition of “on the basis of sex” in the 2020 Rule, the Rule “relies upon . . . the plain meaning of the term in the statute.” 85 Fed. Reg. at 37,178. What plaintiffs advocate is for the inclusion of language *beyond* what is in the text of Section 1557 and Title IX. Indeed, plaintiffs seek more than even the 2016 Rule provided, which declined to include “sexual orientation” in its definition of “on the basis of sex.” *See* 81 Fed. Reg. at 31,390. Plaintiffs provide no legal justification to support such a demand.

Plaintiffs instead rely on a series of cases, which they argue stand for the proposition that “on the basis of sex,” as used in Section 1557, necessarily includes “gender identity” and “sexual orientation.” *See* Mot. at 17–23. Chief among them is the Supreme Court’s recent decision *Bostock v. Clayton County*, 140 S. Ct. 1731 (2020). Specifically, plaintiffs contend that Court’s analysis in that case “applies with full force here and equally guts the Government’s identical interpretation of ‘sex.’” Mot. at 19.⁴ Leaving aside the fact that *Bostock* never interpreted the word “sex,” *see Bostock*, 140 S. Ct. at 1739 (“we proceed on the assumption that ‘sex’ . . . refer[s] only to biological distinctions between male and female”), it is nonsensical to argue that the government’s “interpretation” of “on the basis of sex” is impermissible because, as discussed, the 2020 Rule contains no such interpretation but instead simply incorporates Title IX’s definition. Plaintiffs presumably do not argue that Title IX itself is impermissible even though the text of Title IX does

⁴ Plaintiffs additionally claim that “*Bostock* begins and ends the analysis of the constitutionality of the 2020 Rule,” Mot. at 17, but *Bostock* applied a statute—it did not interpret a constitutional provision.

not use the terms “gender identity” and “sexual orientation.” *See* 20 U.S.C. § 1681(a). Nor does the text of Title VII, for that matter, which was the statute at issue in *Bostock*. *See* 140 S. Ct. at 1738 (citing 42 U.S.C. § 2000e–2(a)(1)). Plaintiffs thus provide no explanation as to why the 2020 Rule’s lack of reference to “gender identity” and “sexual orientation” might render the regulation unlawful when the underlying statute itself does not employ those terms. Plaintiffs cite no authority that would require a regulation to expand upon statutory text. Indeed, HHS could have forgone issuing any rule at all and instead simply relied on the text of Section 1557. *See* 42 U.S.C. § 18116(c) (“The Secretary *may* promulgate regulations to implement this section.” (emphasis added)). Simply put, although plaintiffs complain that the 2020 Rule does not include their preferred language, they provide no argument that HHS was *required* to include a definition of “on the basis of sex,” let alone one that includes the words “gender identity” and “sexual orientation.”

Because plaintiffs cannot identify anything impermissible in the 2020 Rule relating to “on the basis of sex,” they instead take issue with language in the Rule’s preamble rather than its regulatory text. For example, plaintiffs claim that “the 2020 Rule eliminates important nondiscrimination provisions based on sex and interprets ‘sex’ to be solely ‘biological sex.’” *Mot.* at 23 (citing 85 Fed. Reg. at 37,168, 37,177–79, 37,189). But this Court’s focus must remain on the text of the Rule itself, as a regulation’s preamble “lacks the force and effect of law.” *St. Francis Med. Ctr. v. Azar*, 894 F.3d 290, 297 (D.C. Cir. 2018); *see Wyeth v. Levine*, 555 U.S. 555, 575–77 (2009). And, in any event, the Rule’s preamble confirms the permissibility of excluding a definition for “on the basis of sex.” As HHS explained, “to the extent that a Supreme Court decision is applicable in interpreting the meaning of a statutory term, the elimination of a regulatory definition of such term would not preclude application of the Court’s construction.” 85 Fed. Reg. at 37,168. Plaintiffs fail to explain how such a conclusion is impermissible.

Finally, plaintiffs claim that the 2020 Rule runs afoul of Section 1554 of the ACA, which prohibits HHS from promulgating a regulation that “creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care,” “impedes timely access to health care services,” or “interferes with communications regarding a full range of treatment options between the patient and the provider.” 42 U.S.C § 18114(1)–(3); *see* Mot. at 20, 24. Specifically, plaintiffs argue that the 2020 Rule “imposes serious barriers for LGBTQ individuals seeking health care and removes protections to prevent them from being denied care or coverage *solely* because of their gender identity or sexual orientation.” Mot. at 24. But “§ 1554 is meant to prevent direct government interference with health care,” *California by & through Becerra v. Azar*, 950 F.3d 1067, 1094 (9th Cir. 2020) (en banc), and plaintiffs fail to identify any direct interference here. Indeed, if “[t]he most natural reading of § 1554 is that Congress intended to ensure that HHS . . . does not improperly impose regulatory burdens on doctors and patients,” the 2020 Rule’s elimination of regulatory mandates and return to broad incorporation of the specified civil rights statutes goes far toward achieving this end. *See* 85 Fed. Reg. at 37,166.

B. The 2020 Rule Is Not Arbitrary and Capricious.

Plaintiffs argue in the alternative that, even if the 2020 Rule is otherwise lawful, HHS’s reasoning in support was arbitrary and capricious in violation of the APA, 5 U.S.C. § 706(2)(A). *See* Mot. at 24–27. Because the 2020 Rule was supported by HHS’s “reasoned decisionmaking,” *Cooling Water Intake Structure Coal. v. U.S. Evtl. Protec. Agency*, 905 F.3d 49, 67 (2d Cir. 2018), it does not violate the APA.

Aside from its desire to be faithful to the statutory text, one of the more obvious reasons justifying HHS’s decision not to define “on the basis of sex” was the Agency’s desire to avoid wading into an uncertain legal landscape. As HHS observed, there were—and remain— “[c]onflicting views in the lower courts” regarding the application of Title IX. 85 Fed. Reg. at

37,180. Plaintiffs complain that in so noting, HHS “impudently accuses” courts of causing confusion rather than justifying its decision. Mot. at 26. In reality, HHS’s decision not to define “on the basis of sex” was a reasonable one because it allows future courts to interpret Section 1557, and the 2020 Rule, in accordance with current case law. *See* 85 Fed. Reg. at 37,168. Because the 2020 Rule has yet to be applied, it remains to be seen precisely how *Bostock*—which construed a provision of Title VII of the Civil Rights Act of 1964 in the employment context, 140 S. Ct. at 1737—might affect Section 1557, which applies Title IX’s language as a funding provision in the context of healthcare. As HHS noted, while “Title VII case law has often informed Title IX case law with respect to the meaning of discrimination ‘on the basis of sex,’” the definition of “sex” may “take[] on special importance in the health context.” 85 Fed. Reg. at 37,168. The point is that *Bostock*’s applicability to contexts outside of employment discrimination is a question for future courts to decide, as *Bostock* itself made clear. *See* 140 S. Ct. at 1753. It was neither arbitrary nor capricious for HHS to refrain from drafting a rule that attempted to predict prematurely what future precedent might dictate.

Moreover, even if plaintiffs were correct that “cases *overwhelmingly* go against the Department,” Mot. at 26, plaintiffs fail to explain why HHS would have been justified in disregarding *Franciscan Alliance v. Azar*. Plaintiffs opine that it is “[c]urious[]” that “a Texas district court decision from three years ago,” which “enjoined HHS from enforcing certain parts of the 2016 Rule,” *id.* at 9 & n.1, would cause HHS to issue the 2020 Rule. *Franciscan Alliance* did not merely preliminarily enjoin the 2016 Rule in 2016, as plaintiffs claim—it vacated the specific provision plaintiffs now advocate for in 2019. *See* 414 F. Supp. 3d at 947. But even if *Franciscan Alliance* remained a preliminary injunction rather than a vacatur, it was entirely reasonable for HHS to justify not including an expanded definition of “on the basis of sex” when that portion of the 2016 Rule was no longer legally enforceable; indeed, *Franciscan Alliance*

compelled HHS to follow such a course. As the Agency explained, “[t]his final ruling is binding on the Department despite the appellate proceedings still pending in that case: The Department’s Section 1557 regulation, as currently operative, does not contain the 2016 Rule’s definition of ‘on the basis of sex’ to encompass gender identity and termination of pregnancy.” 85 Fed. Reg. at 37,168. Presumably, were plaintiffs to prevail in their case before this Court, they would take exception if HHS decided later to disregard it because it was merely “a [New York] district court decision from three years ago.” Mot. at 9 n.1. The judgment in *Franciscan Alliance* is binding on HHS, and its vacatur of plaintiffs’ desired definition of “on the basis of sex” from the 2016 Rule was reason enough for HHS to release the 2020 Rule in its current form. *See FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 513–16 (2009).

Plaintiffs next criticize HHS’s statement that it “knows of no data showing that the proper enforcement of Federal nondiscrimination law according to statutory text will disproportionately burden individuals on the basis of sexual orientation and/or gender identity.” 85 Fed. Reg. at 37,182; *see* Mot. at 25. Plaintiffs offer nothing to undermine the reasonableness of such a conclusion, but instead reference the quantity of comments received in response to the Rule’s proposal and cite several comments discussed in plaintiffs’ complaint. *See* Mot. at 26. Those comments, however, do nothing other than to highlight past experiences of LGBTQ individuals—necessarily before the 2020 Rule’s promulgation; they do not purport to quantify its effect. *See* Compl. ¶¶ 202–05. Plaintiffs therefore offer nothing to show that HHS’s statement was not an accurate one.

Plaintiffs similarly criticize HHS for relying on supposedly “fuzzy math at best, in asserting that the 2020 Rule will save over \$2 billion,” and observe that not all of these cost savings stem from what they challenge—the lack of a definition for “on the basis of sex.” Mot at 27. These claims relate to a cost-benefit analysis that is not subject to review. HHS did not undertake a cost-

benefit analysis to comply with Section 1557 or the APA, but rather to comply with Executive Orders 12866 and 13563. 85 Fed. Reg. at 37,222. Alleged violations of these “Executive Orders cannot give rise to a cause of action” under the APA. *Fla. Bankers Ass’n v. U.S. Dep’t of Treas.*, 19 F. Supp. 3d 111, 118 n.1 (D.D.C. 2014), *vacated on other grounds*, 799 F.3d 1065 (D.C. Cir. 2015); *see Air Transp. Ass’n v. FAA*, 169 F.3d 1, 8–9 (D.C. Cir. 1999).

Even if the cost-benefit analysis was reviewable, plaintiffs misread the record. First, HHS has predicted \$2.9 billion in savings. Second, HHS has never claimed that all of these savings come from its decision not to define “on the basis of sex.” Instead, HHS made clear that “the largest proportion of these estimated savings would result from repealing the 2016 Rule’s provisions related to mandatory notices.” 85 Fed. at 37,162. Plaintiffs fail to explain how such a conclusion amounts to “fuzzy math” or undermines HHS’s decision not to define “on the basis of sex.”

At bottom, the 2020 Rule was supported by a copious record containing thorough reasoning. HHS acknowledged the changes it was making and provided justifications for doing so. *See Fox*, 556 U.S. at 514 (“We find no basis in the Administrative Procedure Act or in our opinions for a requirement that all agency change be subjected to more searching review.”). That is more than enough to evince the “reasoned decision making” entitling HHS’s decision to deference. *Friends of Animals v. Romero*, 948 F.3d 579, 587 (2d Cir. 2020).

C. The 2020 Rule is Constitutional.

Plaintiffs’ equal protection claims, Mot. at 27–30, are entirely without merit. Because the 2020 Rule does nothing more than repeat the text of Section 1557—a statute whose validity is undisputed—it does not violate the Constitution.

Plaintiffs’ conclusory claim that the “2020 Rule facially discriminates on the basis of a suspect class,” *Id.* at 28, is incorrect. In no way does the 2020 Rule treat LGBTQ individuals

differently than others based on their LGBTQ status.⁵ Neither Section 1557 nor the 2020 Rule “isolate[s] LGBTQ people] or subject[s] them, as a discrete group, to special or subordinate treatment.” *See Schweiker v. Wilson*, 450 U.S. 221, 231 (1981). Instead, LGBTQ “individuals remain protected by the same civil rights laws as any other individual, and [HHS] will vigorously enforce their statutory and regulatory civil rights.” 85 Fed. Reg. at 37,192. “Rather than classifying individuals” by LGBTQ status, Section 1557 and the 2020 Rule *prohibit* others “from classifying individuals” based on several enumerated traits. *See Coal. for Econ. Equity v. Wilson*, 122 F.3d 692, 702 (9th Cir. 1997), *dismissing stay*, 122 F.3d 718 (9th Cir. 1997). The fact that neither Section 1557, nor any of the underlying nondiscrimination statutes it references, nor the 2020 Rule explicitly includes sexual orientation or gender identity among the traits enumerated for special protection from discrimination by others “as a matter of law and logic, does not violate the Equal Protection Clause in any conventional sense.” *See id.*

⁵ Because neither Section 1557 nor the 2020 Rule include a classification on the basis of sexual orientation or transgender status, it is unnecessary to determine the level of scrutiny that might apply to one. But nothing supports plaintiffs’ erroneous assertion that strict scrutiny would ever be applicable. *See Mot.* at 28–29. Of the two cases plaintiffs cite to support that proposition, one stands at most for the application of intermediate—not strict—scrutiny for classifications based on sexual orientation, but not transgender status. *See Windsor v. United States*, 699 F.3d 169, 185 (2d Cir. 2012) (applying intermediate scrutiny classification based on sexual orientation), *aff’d*, 570 U.S. 744 (2013). And the other expressly “d[id] not require [the Court] to reach the question of whether transgender status is per se entitled to heightened scrutiny.” *Whitaker by Whitaker v. Kenosha Unified Sch. Dist. No. 1 Bd. of Educ.*, 858 F.3d 1034, 1051 (7th Cir. 2017), *cert. dismissed*, 138 S. Ct. 1260 (2018). Instead, the *Whitaker* court applied intermediate—not strict—scrutiny to what it found to be a sex-based classification. *Id.* “To date, neither the Supreme Court nor the Second Circuit has held that transgender plaintiffs are members of a protected or suspect class whose equal protection claims are entitled to heightened scrutiny.” *White v. City of New York*, 206 F. Supp. 3d 920, 933 (S.D.N.Y. 2016). “As plaintiff[s] point to no court decision that has found transgender individuals a protected class for the purposes of [equal protection] analysis, . . . rational basis review” would apply. *Lopez v. City of New York*, 2009 WL 229956, at *13 (S.D.N.Y. Jan. 30, 2009). And in any event, even under the 2016 Rule, HHS did not “resolve . . . whether discrimination on the basis of an individual’s sexual orientation status alone is a form of sex discrimination under Section 1557.” 81 Fed. Reg. at 31,390.

Plaintiffs’ assertion that the 2020 Rule reflects an “animus-driven targeting of LGBTQ persons,” Mot. at 28, is based on a faulty premise and, in any event, is unsupported by any “points, either singly or in concert, [that] establish[] a[n]” equal protection claim. *DHS v. Regents of the Univ. of Cal.*, 140 S. Ct. 1891, 1915 (2020). For example, plaintiffs’ assertion that “the [purported] architect of the Rule, Roger Serevino [sic] . . . has made his disdain for the LGBTQ community well-known,” Mot. at 29, is “supported” only by the fact that he criticized the 2016 Rule—noting concerns about its potential conflicts with the beliefs of “[a] lot of religious universities” and “a lot of world religions,” Compl. ¶ 171. And in any event, plaintiffs’ claims arise under the APA, so “the focal point for judicial review should be the administrative record,” not extra-record statements introduced “initially in the reviewing court.” *Camp v. Pitts*, 411 U.S. 138, 142 (1973). These principles are not disregarded because plaintiffs raise a constitutional claim; judicial review under the APA, after all, expressly includes claims that agency action is “contrary to constitutional right.” 5 U.S.C. § 706(2)(B).⁶

Even if the plaintiffs had established a substantial likelihood of a “strong showing of bad faith or improper behavior” necessary to justify extra-record review, *Dep’t of Commerce v. New York*, 139 S. Ct. 2551, 2574 (2019), *remanded*, 2019 WL 3213840 (S.D.N.Y. July 16, 2019)—which they have not—“the cited statements are unilluminating,” *Regents*, 140 S. Ct. at 1916. These statements—“remote in time and made in [the] unrelated context[]” of a private citizen’s personal life before entering government service, *see id.*—reflect reasonable criticisms about the prior rule

⁶ Numerous courts have restricted review to the administrative record in cases raising constitutional claims. *See, e.g., Bellion Spirits, LLC v. United States*, 335 F. Supp. 3d 32, 44 (D.D.C. 2018); *Chiayu Chang v. USCIS.*, 254 F. Supp. 3d 160, 161 (D.D.C. 2017); *Ketcham v. U.S. Nat’l Park Serv.*, Case No. 16-CV-00017-SWS, 2016 WL 4268346, at *1–2 (D. Wyo. Mar. 29, 2016); *Jarita Mesa Livestock Grazing Ass’n v. U.S. Forest Serv.*, 58 F. Supp. 3d 1191, 1237–38 (D.N.M. 2014); *Tafas v. Dudas*, 530 F. Supp. 2d 786, 803 (E.D. Va. 2008); *Harvard Pilgrim Health Care of New England v. Thompson*, 318 F. Supp. 2d 1, 10 (D.R.I. 2004).

in a complex area of social policy, including the effect of the rule on “sincerely held religious beliefs,” see *Masterpiece Cakeshop, Ltd. v. Colo. Civil Rights Comm’n*, 138 S. Ct. 1719, 1729 (2018); nothing about Mr. Severino’s prior public statements indicates that the Final Rule reflects animus toward the LGBTQ community. Indeed, the *Bostock* majority itself cautioned that it was “deeply concerned with preserving the promise of the free exercise of religion,” which “lies at the heart of our pluralistic society,” and acknowledged fears surrounding the intersection of its construction of Title VII with the “religious convictions” of employers. 140 S. Ct. at 1753–54; see also *id.* at 1782 (Alito, J., dissenting) (explaining that Section 1557 challenges based on sex reassignment procedures “present difficult religious liberty issues because some employers and healthcare providers have strong religious objections to sex reassignment procedures”). Statements consistent with those of Justices of the Supreme Court do not amount to a “strong showing of bad faith or improper behavior.” *Commerce*, 139 S. Ct. at 2574.

While relying on statements remote in time and context, plaintiffs ignore the fact that the 2016 Rule was subject to a preliminary injunction and ultimately partial vacatur based on a court’s finding that it was contrary to Section 1557. See *Franciscan All.*, 414 F. Supp. 3d at 946–47. Aligning the regulation with the text of Section 1557 in an effort to minimize litigation risk is a much more “obvious alternative explanation” for the Final Rule than animus. See *Ashcroft v. Iqbal*, 556 U.S. 662, 682 (2009) (citation omitted). As explained throughout the rulemaking, and *supra*, HHS’s Final Rule is rationally related to several legitimate government interests. See *Cooper Hosp./Univ. Med. Ctr. v. Burwell*, 179 F. Supp. 3d 31, 47 (D.D.C. 2016) (describing “[r]eview of an equal protection claim in the context of agency action”) (citations omitted).

Plaintiffs’ heavy reliance on *Romer v. Evans*—which involved a constitutional provision of an entirely distinct scope and impact from the 2020 Rule—is misplaced. In *Romer*, the Court determined that a Colorado State Constitution provision violated the Equal Protection Clause when

it did “more than repeal or rescind” particular ordinances that prohibited discrimination on the basis of sexual orientation, and instead “prohibit[ed] all legislative executive or judicial action at any level of state or local government designed to protect the named class.” 517 U.S. 620, 624 (1996). The 2020 Rule, at most, approaches the former; it comes nowhere near the latter. Indeed, HHS explained that “[s]tates and localities do indeed manifest a range of different views on what specific protections should be accorded to the categories of sexual orientation and gender identity in civil rights law” and that the 2020 Rule does not “preempt States’ diverse views on these topics.” 85 Fed. Reg. at 37,182. What is more, the 2020 Rule does not “prevent covered entities from maintaining or adopting” policies that protect patients from discrimination based on LGBTQ status “or endorsing a variety of theories of gender identity.” *See id.* at 37,191.

III. PLAINTIFFS HAVE NOT DEMONSTRATED IRREPARABLE HARM

“[I]rreparable harm is the single most important prerequisite for the issuance of a preliminary injunction, and . . . accordingly, the moving party must first demonstrate that such injury is likely before the other requirements for the issuance of an injunction will be considered.” *Grand River Enter. Six Nations, Ltd. v. Pryor*, 481 F.3d 60, 66–67 (2d Cir. 2007) (citation omitted). “To satisfy this requirement, Plaintiff ‘must demonstrate that absent a preliminary injunction [he] will suffer an injury that is neither remote nor speculative, but actual and imminent, and one that cannot be remedied if a court waits until the end of trial to resolve the harm.’” *Raia v. Pompeo*, -- F. Supp. 3d --, 2020 WL 1921573, at *3 (E.D.N.Y. Apr. 21, 2020) (citing *Faiveley Transp. Malmö AB v. Wabtec Corp.*, 559 F.3d 110, 118 (2d Cir. 2009)). A preliminary injunction cannot be entered based on a mere “possibility” of irreparable harm. *Winter*, 555 U.S. at 22. Instead, the threat of irreparable injury must be “real,” “substantial,” and “immediate.” *City of Los Angeles*, 461 U.S. at 111. Plaintiffs’ “speculative” assertions of harm by unknown individuals come nowhere close to satisfying that standard here. *Id.*

First, plaintiffs contend that the 2020 Rule exposes them to “discriminatory, verbally abusive treatment, sub-standard care, or a denial of coverage for medical treatments.” Mot. at 12. To the extent that plaintiffs complain about the Rule not including a definition of “on the basis of sex,” plaintiffs fail to articulate how defendants will cause irreparable harm because the prior rule that plaintiffs prefer has been vacated in relevant part and would not control even if the 2020 Rule were invalidated. *See Franciscan All.*, 414 F. Supp. 3d at 947.

As to plaintiffs’ other criticisms regarding the potential for discrimination or poor care, plaintiffs speculate that third parties—not the government—will engage in conduct they oppose. *See supra* I.B. Plaintiffs rely on a hypothetical factual chain in which they seek medical attention at some later date and not only encounter a medical professional who engages in the conduct plaintiffs dislike, but also that the medical professional would not have engaged in that behavior in the absence of the 2020 Rule—an especially unlikely event, given that the *Franciscan Alliance* vacatur is still in effect and would prevent the relevant portions of the 2016 Rule from being in effect regardless of the 2020 Rule. That necessarily renders the possibility of future harm wholly speculative. But “a plaintiff must show that he has sustained or is immediately in danger of sustaining some direct injury as the result of the challenged conduct, one that is not conjectural or speculative.” *N.Y. State Nat. Org. for Women v. Terry*, 886 F.2d 1339, 1347 (2d Cir. 1989) (citation omitted); *see also Kaplan v. Bd. of Educ. of City Sch. Dist. of City of N.Y.*, 759 F.2d 256, 259 (2d Cir. 1985) (plaintiffs’ hypothetical allegations of “havoc and unrest” in response to new city policy were “too speculative to constitute a clear showing of immediate irreparable harm”); *Wis. Gas Co. v. FERC*, 758 F.2d 669, 674 (D.C. Cir. 1985) (“Injunctive relief ‘will not be granted against something merely feared as liable to occur at some indefinite time.’” (quoting *Connecticut v. Massachusetts*, 282 U.S. 660, 674 (1931))); *see also Raia*, 2020 WL 1921573, at *5 (E.D.N.Y. Apr. 21, 2020) (finding “the remedy . . . is too attenuated from the alleged irreparable harm

because it relies on too many unknowns” such that plaintiff had not established irreparable harm) (citing *Shain v. Ellison*, 356 F.3d 211, 216 (2d Cir. 2004) (finding “an accumulation of inferences is simply too speculative and conjectural to supply a predicate for prospective injunctive relief”). Tellingly, plaintiffs’ alleged instances of discrimination necessarily could not have been caused by the 2020 Rule, which has yet to take effect. *See, e.g.*, Mot. at 4 (noting that Walker was subjected to “misgendering, outing, physically abusive treatment, neglect, harassment, and embarrassment” in 2017), *id.* at 5 (noting that Gentili went for an appointment with a doctor who refused treatment sometime before 2004). Plaintiffs’ allegations of discrimination before the 2020 Rule do not show that the 2020 Rule will cause discrimination.

Second, plaintiffs contend that the 2020 Rule will leave them “without federal redress” in the event of discrimination. It appears that plaintiffs are asserting the 2020 Rule eliminates an existing private right of action, but they are mistaken. Any private right of action must come from the underlying statute. *Alexander v. Sandoval*, 532 U.S. 275, 291 (2001) (“Language in a regulation may invoke a private right of action that Congress through statutory text created, but it may not create a right that Congress has not.”). The 2016 Rule asserted that § 1557 contained a private right of action. 81 Fed. Reg. at 31,472 (previously codified at 45 C.F.R. § 92.302(d)). The 2020 Final Rule does not purport to eliminate any such private right of action; instead, HHS explained that the removal of that regulatory provision shows that HHS does not “intend[] to take a position in its regulations on the issue of whether Section 1557 provides a private right of action.” 85 Fed. Reg. at 37,203. Thus, any private right of action available under § 1557 remains available under § 1557, and the Rule creates no risk of harm. A plaintiff under the 2016 Rule would be able to bring a private claim for a § 1557 violation only were the statute itself (or the relevant underlying statute incorporated by reference) to contain a private right of action, and the same is true under the 2020 Rule.

Third, plaintiffs assert an amorphous claim that the *mere existence* of the 2020 Rule will create irreparable harm because it will make plaintiffs feel “marginalized,” and that those feelings of marginalization will lead to “genuine distress, anxiety, discomfort, and humiliation.” Mot. at 14 (quoting *Evancho v. Pine-Richland Sch. Dist.*, 237 F. Supp. 3d 267, 294 (W.D. Pa. 2017)). But plaintiffs’ subjective feelings of disagreement and unhappiness with a federal regulation are not a legally cognizable injury. Plaintiffs rely on a set of cases that found some form of emotional distress to be sufficient to show irreparable harm, but those cases all involved plaintiffs who were singled out for disfavored governmental treatment that itself allegedly caused the humiliation or the discomfort, such as a school district’s change policy that required plaintiffs not to use bathrooms designated for persons of the opposite biological sex. See *Whitaker By Whitaker*, 858 F.3d at 1045; *Evancho v. Pine-Richland Sch. Dist.*, 237 F. Supp. 3d 267, 293–94 (W.D. Pa. 2017). Those cases do not support the idea that plaintiffs suffer irreparable harm simply because they believe that a government’s prospective and generally applicable interpretation of federal law “sends ‘a message’” that certain people “are ‘outsiders.’” Mot. 14 (citation omitted). If a plaintiff suffers irreparable injury just because the plaintiff is distressed that the law sends the wrong message, the requirement of irreparable injury has been reduced to a nullity and Article III standing would require nothing beyond such a generalized grievance.

Fourth, plaintiffs claim that they will also suffer irreparable injury because they will fear discrimination under the 2020 Rule, and that fear will lead them to avoid seeking medical care. But that claim simply seeks to repackage their unfounded theory that the 2020 Rule will make them suffer discrimination in the future. That hypothetical future harm is not certainly impending, and plaintiffs “cannot manufacture standing merely by inflicting harm on themselves based on their fears of hypothetical future harm that is not certainly impending.” *Clapper*, 568 U.S. at 416.

Fifth, plaintiffs claim that any constitutional injury is a *per se* irreparable injury. But, as

discussed *supra*, plaintiffs have not made out an equal protection claim at all, and they have not shown their own equal protection rights would be violated.

In sum, plaintiffs have failed to show that they will suffer irreparable harm if the 2020 Rule goes into effect.

IV. THE BALANCE OF THE EQUITIES & THE PUBLIC INTEREST FAVOR DEFENDANTS

The balance of hardships and the public interest weigh against issuing an injunction here. Where the government is a party, these two inquiries merge. *Nken*, 556 U.S. at 435. There is inherent harm to an agency in preventing it from implementing regulations that Congress has found to be in the public interest to direct that agency to develop. *Maryland v. King*, 567 U.S. 1301 (2012) (Roberts, C.J., in chambers) (stating that the Government will “suffer[] a form of irreparable injury” if it “is enjoined by a court from effectuating statutes enacted by representatives of its people.”).

Furthermore, the 2020 Rule is extensive and deals with a number of discrete topics relating to Section 1557, and plaintiffs have not even argued that enjoining any other provision would benefit the public interest. Plaintiffs have not shown, for example, that the public interest benefits from enjoining the 2020 Rule’s repeal of burdensome notice and tagline requirements, and HHS has documented that those notice requirements imposed hundreds of millions of dollars a year of unanticipated and unnecessary costs on covered entities and provided little, if any, benefit. 84 Fed. Reg. at 27,857–58. Plaintiffs address only one provision of the 2020 Rule, and the vacatur in *Franciscan Alliance* means that plaintiffs cannot get even some of their preferred regulatory provision reinstated with a preliminary injunction of the 2020 Rule. The other harms discussed by HHS and mitigated by the 2020 Rule’s other provisions will return in force if this Court grants preliminary relief. That is unquestionably harm that outweighs plaintiffs’ asserted injuries, which,

as discussed above, are noncognizable, unsupported by anything other than conclusory allegations, and insufficiently substantial to warrant an injunction.

V. NATIONWIDE RELIEF IS INAPPROPRIATE

Even if the Court were to disagree with defendants' arguments, any preliminary injunctive relief should be no broader than necessary to provide plaintiffs with relief and therefore should extend only to the named plaintiffs. "A plaintiff's remedy must be tailored to redress the plaintiff's particular injury," *Gill v. Whitford*, 138 S. Ct. 1916, 1934 (2018), and "injunctive relief should be no more burdensome to the defendant than necessary to provide complete relief to the plaintiffs," *Madsen v. Women's Health Ctr., Inc.*, 512 U.S. 753, 765 (1994) (quoting *California v. Yamasaki*, 442 U.S. 682, 702 (1979)); see also *Trump v. Hawaii*, 138 S. Ct. 2392, 2429 (2018) (Thomas, J., concurring) (noting that nationwide injunctions "are legally and historically dubious"), *remanded*, 898 F.3d 1266 (9th Cir. 2018); *DHS v. New York*, 140 S. Ct. 599, 600 (2020) (Gorsuch, J., concurring in the granting of a stay) ("Universal injunctions have little basis in traditional equitable practice"), *denying modification*, 2020 WL 1969276 (U.S. Apr. 24, 2020). These principles apply with even greater force to a preliminary injunction, an equitable tool designed merely to "preserve the relative positions of the parties until a trial on the merits can be held." *Univ. of Tex. v. Camenisch*, 451 U.S. 390, 395 (1981).

Entering broad relief would be particularly inappropriate here because the Rule is being challenged in other courts. See *Whitman-Walker Clinic, Inc. v. HHS*, No. 1:20-cv-1630 (D.D.C.); *Boston Alliance of Gay, Lesbian, Bisexual & Transgender Youth v. HHS*, No. 1:20-cv-11297 (D. Mass.); *Washington v. HHS*, No. 1:20-cv-1105 (W.D. Wash.); *New York v. HHS*, 1:20-cv-5583 (S.D.N.Y.). If the government prevails in all four other jurisdictions, a nationwide injunction would render those victories meaningless as a practical matter. See *New York*, 140 S. Ct. at 601 (Gorsuch, J., concurring in the granting of a stay) ("If a single successful challenge is enough to

stay the challenged rule across the country, the government's hope of implementing any new policy could face the long odds of a straight sweep."). It would also preclude appellate courts from testing plaintiffs' challenges to the Rule's operation in other jurisdictions.

Moreover, nationwide injunctions "take a toll on the federal court system—preventing legal questions from percolating through the federal courts, encouraging forum shopping, and making every case a national emergency for the courts and for the Executive Branch." *Hawaii*, 138 S. Ct. at 2425 (Thomas, J., concurring). Non-plaintiff entities may prefer for the Rule to take effect, affording them certainty regarding the obligations of covered entities in protecting important nondiscrimination rights. For the same reasons, a stay of the effective date pursuant to 5 U.S.C. § 705 is not warranted. *Affinity Healthcare Servs., Inc. v. Sebelius*, 720 F. Supp. 2d 12, 15 n.4 (D.D.C. 2010) ("Motions to stay agency action pursuant to these provisions are reviewed under the same standards used to evaluate requests for interim injunctive relief.").

In addition, should the Court enjoin any portion of the Rule, it should allow the remainder to go into effect. In determining whether severance is appropriate, courts look to both the agency's intent and whether the regulation can function sensibly without the excised provision(s). *MD/DC/DE Broads. Ass'n v. FCC*, 236 F.3d 13, 22 (D.C. Cir. 2001). There is no question that the agency intended the rule to be severable, as it retained the 2016 Rule's severability provision. 85 Fed. Reg. at 37,245 (codified at 45 C.F.R. § 92.3(d)). Likewise, plaintiffs have not explained how enjoining the discrete portion of the 2020 Rule they challenge would prevent the other portions of the 2020 Rule from functioning sensibly. The 2020 Rule covers a broad range of issues relating to obligations under Section 1557 of the ACA, and plaintiffs challenge only a discrete portion of that Rule. Plaintiffs have not explained how, for example, a narrower injunction would affect whether the Rule's repeal of costly notice-and-tagline provisions relating to language access could function sensibly. Plaintiffs also have not challenged every provision of the Rule, and they bear the burden

to establish an entitlement to an injunction. *Winter*, 555 U.S. at 20; *cf. Printz v. United States*, 521 U.S. 898, 935 (1997) (Courts “have no business answering” questions about the validity of provisions that concern only “the rights and obligations of parties not before [them]”). Plaintiffs have identified no functional reason the entire Rule must fall if the Court were to agree only with plaintiffs’ attacks on a particular provision, and this Court should accordingly not issue relief beyond the challenged provision.

CONCLUSION

For the foregoing reasons, defendants respectfully request that this Court (i) deny plaintiffs’ motion for a preliminary injunction; and (ii) grant any such other and further relief as this Court deems just and proper.

Dated: Brooklyn, New York
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