XAVIER BECERRA
Attorney General of California
KATHLEEN BOERGERS, State Bar No. 213530
NELI N. PALMA, State Bar No. 203374
KARLI EISENBERG, State Bar No. 281923
STEPHANIE T. YU, State Bar No. 294405
1300 I Street, Suite 125, P.O. Box 944255
Sacramento, CA 94244-2550
Tel: (916) 210-7522; Fax: (916) 322-8288
E-mail: Neli.Palma@doj.ca.gov
Attorneys for Plaintiff State of California, by and through Attorney General Xavier Becerra

JAMES R. WILLIAMS, State Bar No. 271253
County Counsel
GRETA S. HANSEN, State Bar No. 251471
LAURA S. TRICE, State Bar No. 284837
MARY E. HANNA-WEIR, State Bar No. 320011
SUSAN P. GREENBERG, State Bar No. 318055
H. LUKE EDWARDS, State Bar No. 313756
Office of the County Counsel, Cty. of Santa Clara
70 West Hedding Street, East Wing, 9th Fl.
San José, CA 95110-1770
Tel: (408) 299-5900; Fax: (408) 292-7240
Email: mary.hanna-weir@cco.sccgov.org
Attorneys for Plaintiff County of Santa Clara

DENNIS J. HERRERA, State Bar No. 139669
City Attorney
JESSE C. SMITH, State Bar No. 122517
Chief Assistant City Attorney
RONALD P. FLYNN, State Bar No. 184186
Chief Deputy City Attorney
YVONNE R. MERÉ, State Bar No. 173594
SARA J. EISENBERG, State Bar No. 269303
JAIME M. HULING DELAYE, State Bar No. 270784
Deputy City Attorneys
City Hall, Rm 234, 1 Dr. Carlton B. Goodlett Pl.
San Francisco, CA 94102-4602
Tel: (415) 554-4633, Fax: (415) 554-4715
E-Mail: Sara.Eisenberg@sfcityatty.org
Attorneys for Plaintiff City and County of San Francisco

LEE H. RUBIN, State Bar No. 141331
Mayer Brown LLP
3000 El Camino Real, Suite 300,
Palo Alto, CA 94306-2112
Tel: (650) 331-2000, Fax: (650) 331-2060
Email: lrubin@mayerbrown.com
Attorneys for Plaintiffs County of Santa Clara, et al.

**Additional Counsel Listed on Signature Pages*

IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

CITY AND COUNTY OF SAN FRANCISCO, Plaintiff, vs. ALEX M. AZAR II, et al., Defendants.	No. C 19-02405 WHA No. C 19-02769 WHA No. C 19-02916 WHA **PLAINTIFFS' RESPONSE TO ORDER RE USE OF TERM "ENTITY"**
STATE OF CALIFORNIA, by and through ATTORNEY GENERAL XAVIER BECERRA, Plaintiff, vs. ALEX M. AZAR, et al., Defendants.	Date: October 30, 2019 Time: 8:00 AM Courtroom: 12 Judge: Hon. William H. Alsup Action Filed: 5/2/2019
COUNTY OF SANTA CLARA, et al. Plaintiffs, vs. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al., Defendants.	

I. THE 2019 RULE'S DEFINITION OF "ENTITY" INCLUDES "HEALTH CARE ENTITIES"

The answer to the question posed in the Court's November 8, 2019 Order is yes. Church does not use the term "health care entity," only "entity." The Rule, however, defines the term "entity" to include essentially anyone, including all health care entities. It defines "entity" as:

> a 'person' as defined in 1 U.S.C. 1; the Department; a State, political subdivision of any State, instrumentality of any State or political subdivision thereof; any public agency, public institution, public organization, or other public entity in any State or political subdivision of any State; or, as applicable, a foreign government, foreign nongovernmental organization, or intergovernmental organization . . . .

84 Fed. Reg. 23,263 (Section 88.2). In turn, Section 1 of the U.S. Code defines "person" to "include corporations, companies, associations, firms, partnerships, societies, and joint stock companies, as well as individuals." In other words, HHS's "entity" definition includes—without limitation—any corporation, company, individual, government, or public agency.[1] The subset of corporations, companies, individuals, and public entities that also qualify as "health care entities" under the Rule *necessarily* fall within this capacious definition of "entity."

The regulatory history of the terms "entity" and "health care entity" supports this conclusion. The 2019 Rule seeks to "generally reinstate" HHS's 2008 rule.[2] 84 Fed. Reg. 23,179. In that earlier rule, HHS subsumed the term "entity" as used in Church under the definition of "health care entity" as used in Weldon and Coats-Snowe. *See* 73 Fed. Reg. 78,072, 78,076 (Dec. 19, 2008) ("[T]he Department thought it would be beneficial to provide a clear and consistent definition that it would apply when implementing any of the three statutes."); *id*. at 78,091 (Church "does not define the term 'entity,' and does not use the term 'health care entity.' In keeping with the definitions in PHS Act § 245 and the Weldon Amendment, the Department proposed to define 'health care entity' to include the specifically mentioned types of individuals

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[1] HHS has argued that although there is no limiting principle within the definition of "entity" itself, "[f]or some statutes . . . , the Applicability paragraph [of the Rule] by its own terms may only implicate certain types of entities or only entities receiving certain types of funding." 84 Fed. Reg. 23,170. While the Applicability paragraph concerning the Church Amendment indicates that it applies only to entities that receive certain funding, nothing in that paragraph limits the types of entities covered. *Id.* at 23,264-65 (Section 88.3(a)(1)).

[2] The 2008 rule never meaningfully went into effect. *See New York v. v. U.S. Dep't of Health & Human Servs.*, 2019 WL 5781789, at *8–*9 (S.D.N.Y. Nov. 6, 2019). It became effective on January 20, 2009 without the certification requirements and was rescinded by the 2011 rule on February 23, 2011. During that period, it appears it was not enforced. *Id*. at *8.

and organizations from the two statutes, as well as other types of entities referenced in the Church Amendments."). While the 2008 rule used identical definitions for the terms "entity" and "health care entity," *id*. at 78,097, the 2019 Rule is even broader, going beyond the definitions covered by the 2008 Rule. 84 Fed. Reg. 23,179, 23,263.[3]

Defendants may argue that the 2019 Rule attempts to limit "health care entity"—contending that it applies only to instances specific to Weldon, Coats-Snowe, and ACA Section 1553. But the 2019 Rule makes clear that "health care entity" applies broadly to *any* circumstance in which a conscience objection may be made. *Id*. at 23,184 ("If the Department becomes aware that a State or local government or a health care entity may have undertaken activities that may violate *any* statutory conscience protection…") (emphasis added); 23,194–96 ("health care entity" encompasses a non-exclusive list that may vary case-by-case).[4] This renders unavailing any argument by HHS that the 2019 Rule applies the term "health care entity" only to statutes that include that term—namely, Weldon, Coats-Snowe, and ACA Section 1553.

II. HHS'S DEFINITION OF "ENTITY" CONFLICTS WITH CHURCH

HHS's definition of the term "entity" conflicts with Church. As an initial matter, the language, context, and legislative history of Church establish that it was intended to apply to those with a close nexus to the procedure, like doctors and nurses, as well as religious hospitals. By defining entity broadly enough to sweep in countless others, HHS has contravened Congress's will. Moreover, both Coats-Snowe and Weldon define "health care entity" to include both individuals and certain institutions. *See* 42 U.S.C. § 238n(c)(2); 132 Stat. 2981, 3118. But Church carefully distinguishes between an "entity" and an "individual," with some provisions applying to entities, some applying to individuals, and some applying to both. *See*, *e.g.*, 42 U.S.C. § 300a-7(b) ("The receipt of any grant, contract, loan, or loan guarantee under [the covered Acts] by any

[3] In 2011, HHS rescinded the 2008 definitions, stating that the 2008 Rule had "caused confusion regarding the scope of the federal health care provider conscience protection statutes" and might "negatively affect the ability of patients to access care if interpreted broadly." 76 Fed. Reg. at 9973–74; *see also New York*, 2019 WL 5781789, at *9. HHS's failure even to acknowledge that the 2011 rule rescinded the previous definition for fear of creating confusion is arbitrary and capricious. *New York*, 2019 WL 5781789, at *46.

[4] *See also* https://www.hhs.gov/sites/default/files/final-conscience-rule-factsheet.pdf (combining conscience protections of various provisions as protecting "health care entities and employees").

1 *individual or entity* does not authorize any court or any public official or other public authority to
2 require -- (1) such *individual* to [take certain actions], or (2) such *entity* to [take certain actions]");
3 *id.* § 300a-7(c) (imposing requirements on "entit[ies]"); *id.* § 300a-7(d) (granting certain
4 protections to an "individual"). It is clear from this language that the term "entity," as used in
5 Church, was intended to exclude individual persons. *See S.E.C. v. McCarthy*, 322 F.3d 650, 656
6 (9th Cir. 2003) ("It is a well-established canon of statutory interpretation that the use of different
7 words or terms within a statute demonstrates that Congress intended to convey a different
8 meaning for those words."). Therefore, the term "entity" as used in Church cannot encompass the
9 term "health care entity" as used in either Coats-Snowe or Weldon, because the phrase as defined
10 in those provisions includes specified categories of individuals.

11 **III. THE SUBSTANTIVE EXPANSION OF THE CHALLENGED DEFINITIONS REQUIRES**
12 **VACATUR**

13 The Rule's expansion of the definition of "entity" is but one of numerous ways that the
14 Rule exceeds the scope of HHS's authority, making vacatur the appropriate remedy. *New York* ,
15 2019 WL 5781789, at *24, *29, *66 (vacating the Rule because, *inter alia*, HHS lacked authority
16 to substantively alter statutory definitions). Indeed, this Court need look no further than the
17 definitions of the terms "assist in the performance," "refer," "healthcare entity," and
18 "discrimination" to vacate the Rule, as those definitions go to the heart of the Rule and create a
19 new system for refusals and accommodation. Congress did not grant HHS the authority to
20 construe Church to cover such a broad range of funding recipients—imposing substantive
21 obligations and creating refusal rights and enforcement powers never contemplated in the statute.
22 *New York*, 2019 WL 5781789, at *29, *33, *66-67 ("With respect to the Church, Coats-Snowe,
23 and Weldon Amendments, HHS was never delegated and did not have substantive rule-making
24 authority"); Pls.' Mot. 27-30; Pls.' Reply 3-7. Based on these and several other independent
25 violations of the APA demonstrated by Plaintiffs, as well as the Rule's constitutional infirmities,
26 vacatur of the Rule is warranted. *New York*, 2019 WL 5781789, at *67-72 (citations omitted);
27 Pls.' Mot. 30-35, 54-55; Pls.' Reply 3-7, 20.
28

Respectfully Submitted,

Dated: November 12, 2019

XAVIER BECERRA
Attorney General of California
KATHLEEN BOERGERS
Supervising Deputy Attorney General

/s/ Neli N. Palma

NELI N. PALMA
KARLI EISENBERG
STEPHANIE T. YU
Deputy Attorneys General
Attorneys for Plaintiff State of California, by and through Attorney General Xavier Becerra

Dated: November 12, 2019

DENNIS J. HERRERA
City Attorney
JESSE C. SMITH
RONALD P. FLYNN
YVONNE R. MERÉ
SARA J. EISENBERG
JAIME M. HULING DELAYE
Deputy City Attorneys

By: */s/ Sara J. Eisenberg*

SARA J. EISENBERG
Deputy City Attorney
Attorneys for Plaintiff City and County of San Francisco

Dated: November 12, 2019

By: */s/ Lee H. Rubin*

LEE H. RUBIN
lrubin@mayerbrown.com
Mayer Brown LLP
Two Palo Alto Square, Suite 300
3000 El Camino Real
Palo Alto, California 94306-2112
Tel: (650) 331-2000

MIRIAM R. NEMETZ*
mnemetz@mayerbrown.com
NICOLE SAHARSKY*
nsaharsky@mayerbrown.com
ANDREW TAUBER*
Mayer Brown LLP
1999 K Street, Northwest
Washington, DC 2006-1101
Tel: (202) 263-3000
Counsel for Plaintiffs County of Santa Clara, Trust Women Seattle, Los Angeles LGBT Center, Whitman-Walker Clinic, Inc. d/b/a Whitman-Walker Health, Bradbury Sullivan LGBT Community Center, Center on Halsted, Hartford Gyn Center, Mazzoni Center, Medical Students For Choice, AGLP: The Association of LGBT+Psychiatrists, American Association of Physicians For Human Rights d/b/a GLMA: Health Professionals Advancing LGBT Equality, Colleen McNicholas, Robert Bolan, Ward Carpenter, Sarah Henn, and Randy Pumphrey

Dated: November 12, 2019

By: */s/ Mary E. Hanna-Weir*

JAMES R. WILLIAMS
County Counsel
GRETA S. HANSEN
Chief Assistant County Counsel
LAURA S. TRICE
Lead Deputy County Counsel
MARY E. HANNA-WEIR
SUSAN P. GREENBERG
H. LUKE EDWARDS
Deputy County Counsels
mary.hanna-weir@cco.sccgov.org
Office of the County Counsel,
County of Santa Clara
70 West Hedding Street, East Wing, 9th Floor
San José, California 95110-1770
Tel: (408) 299-5900
Counsel for Plaintiff County of Santa Clara

Dated: November 12, 2019

By: */s/ Richard B. Katskee*

RICHARD B. KATSKEE*
katskee@au.org
KENNETH D. UPTON, JR.*
upton@au.org
Americans United for Separation
of Church and State
1310 L Street NW, Suite 200
Washington, DC 20005
Tel: (202) 466-3234
Counsel for Plaintiffs Trust Women Seattle, Los Angeles LGBT Center, Whitman-Walker Clinic, Inc. d/b/a Whitman-Walker Health, Bradbury Sullivan LGBT Community Center, Center on Halsted, Hartford Gyn Center, Mazzoni Center, Medical Students For Choice, AGLP: The Association of LGBT+Psychiatrists, American Association of Physicians For Human Rights d/b/a GLMA: Health Professionals Advancing LGBT Equality, Colleen McNicholas, Robert Bolan, Ward Carpenter, Sarah Henn, and Randy Pumphrey

Dated: November 12, 2019

By: */s/ Genevieve Scott*

GENEVIEVE SCOTT*
gscott@reprorights.org
RABIA MUQADDAM*
rmuqaddam@reprorights.org
Center for Reproductive Rights
199 Water Street, 22nd Floor
New York, NY 10038
Tel: (917) 637-3605
Counsel for Plaintiffs Trust Women Seattle, Los Angeles LGBT Center, Whitman-Walker Clinic, Inc. d/b/a Whitman-Walker Health, Bradbury Sullivan LGBT Community Center, Center on Halsted, Hartford Gyn Center, Mazzoni Center, Medical Students For Choice, AGLP: The Association of LGBT+Psychiatrists, American Association of Physicians For Human Rights d/b/a GLMA: Health Professionals Advancing LGBT Equality, Colleen McNicholas, Robert Bolan, Ward Carpenter, Sarah Henn, and Randy Pumphrey

Dated: November 12, 2019

By: */s/ Jamie A. Gliksberg*

JAMIE A. GLIKSBERG*
jgliksberg@lambdalegal.org
CAMILLA B. TAYLOR*
ctaylor@lambdalegal.org
Lambda Legal Defense and
Education Fund, Inc.
105 West Adams, 26th Floor
Chicago, IL 60603-6208
Tel: (312) 663-4413

OMAR GONZALEZ-PAGAN*
ogonzalez-pagan@lambdalegal.org
Lambda Legal Defense and
Education Fund, Inc.
120 Wall Street, 19th Floor
New York, NY 10005-3919
Tel: (212) 809-8585

PUNEET CHEEMA*
pcheema@lambdalegal.org
Lambda Legal Defense and
Education Fund, Inc.
1776 K Street NW, 8th Floor
Washington, DC 20006
Tel: (202) 804-6245, ext. 596
Counsel for Plaintiffs Trust Women Seattle, Los Angeles LGBT Center, Whitman-Walker Clinic, Inc. d/b/a Whitman-Walker Health, Bradbury Sullivan LGBT Community Center, Center on Halsted, Hartford Gyn Center, Mazzoni Center, Medical Students For Choice, AGLP: The Association of LGBT+Psychiatrists, American Association of Physicians For Human Rights d/b/a GLMA: Health Professionals Advancing LGBT Equality, Colleen McNicholas, Robert Bolan, Ward Carpenter, Sarah Henn, and Randy Pumphrey

* *Admitted pro hac vice*