UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT

PLANNED PARENTHOOD FEDERATION OF AMERICA, INC. and PLANNED PARENTHOOD OF CONNECTICUT, INC., Plaintiffs, v. MICHAEL O. LEAVITT, Secretary of the United States Department of Health and Human Services, in his official capacity, Defendant.	Civil Action No. _____ January 15, 2009

COMPLAINT

I. INTRODUCTORY STATEMENT

1. This is a challenge, pursuant to the Administrative Procedure Act ("APA") and the United States Constitution, to a regulation promulgated by the U.S. Department of Health and Human Services ("HHS") on December 19, 2008, which is scheduled to be effective on January 20, 2009, entitled "Ensuring That Department of Health and Human Services Funds Do Not Support Coercive or Discriminatory Policies or Practices in Violation of Federal Law" ("Regulation," "Rule," or "Provider Conscience Regulation"). 73 Fed. Reg. 78,072 (Dec. 19, 2008) (to be codified at 45 C.F.R. pt. 88). A copy of the Regulation is attached as Exhibit A.

2. The Regulation purports to "implement[]" and "enforce[]" three federal statutes that have long been part of federal law without any previous HHS guidance or regulation. 73 Fed. Reg. 78,096. Despite the long existence of these federal laws, Defendant proposed the Regulation on August 26, 2008; provided only thirty days for public comment; and attempted (unsuccessfully, as set out below) to respond to approximately 200,000 comments in less than

three months, before issuing the final regulation on December 19, 2008 – thirty-two days before leaving office.

3. The Regulation dramatically expands the underlying laws, thereby threatening the health of women and men who will be improperly denied access to vital health care services and information, even in life-threatening situations. Moreover, in its rush to finalize the Regulation, HHS failed to follow the appropriate regulatory steps, including failing to respond adequately to the many comments that raised significant problems with the Regulation, and improperly calculating its impact. Finally, by failing to set forth clear standards under which Plaintiffs must operate if they are to maintain their federal funding, by requiring absolute accommodation of employees with religious objections, and by creating significant barriers to obtaining life-saving abortions, the Regulation also threatens the constitutional rights of Plaintiffs and their patients.

4. For all of these reasons, Plaintiffs seek a judgment declaring the Regulation arbitrary, capricious, an abuse of discretion, not in accordance with law, in excess of statutory authority, without observance of procedure required by law in violation of the APA, and in violation of the First and Fifth Amendments to the United States Constitution, and an order permanently enjoining the Regulation and remanding it to HHS for such further administrative proceedings as may be appropriate.

II. JURISDICTION AND VENUE

5. Jurisdiction is conferred on this Court by 28 U.S.C. § 1331.

6. This action is authorized by the Administrative Procedure Act, 5 U.S.C. § 551 *et seq.* as well as 28 U.S.C. § 1331. Plaintiffs' claim for declaratory and injunctive relief is authorized by 28 U.S.C. §§ 2201 and 2202.

7. Venue is appropriate under 28 U.S.C. § 1391(e) because administrative offices and healthcare facilities of Plaintiff Planned Parenthood of Connecticut, Inc. ("PPC") are located in this district. Therefore, a substantial part of the events or omissions giving rise to Plaintiffs' claims occur in this district.

III. PARTIES

A. Plaintiffs

8. Plaintiff Planned Parenthood Federation of America ("PPFA") is a not-for-profit corporation organized under the laws of New York. PPFA is the leading national voluntary health organization in the field of reproductive health care. PPFA has 97 member-affiliates in 49 states and the District of Columbia.

9. Planned Parenthood member-affiliates provide a wide range of reproductive health services at their health care centers including: pregnancy diagnosis and counseling; contraceptive counseling; provision of all methods of contraception, including emergency contraception; HIV/AIDS testing and counseling; testing, diagnosis, and treatment of sexually transmitted infections; cancer screening for cervical and breast cancer; and medication and surgical abortions.

10. Cumulatively, Planned Parenthood's member-affiliates have more than 870 health centers that serve over 3 million patients per year with a wide range of reproductive health care services and education. For example, in 2007, more than 2 million women and men sought contraceptive services from Planned Parenthood member-affiliates; Planned Parenthood member-affiliates provided pregnancy tests to more than 1 million women; provided emergency contraceptive services to nearly 1.5 million women; provided prenatal care to over 10,000 women; provided screening and/or treatment for sexually transmitted infections to more than 3.5

million women and men; provided HIV testing to an additional 368,000 women and men; and provided abortion services to approximately 300,000 women.

11. Most of PPFA affiliates' patients are poor and/or uninsured. The majority have incomes at or below 150% of the federal poverty level.

12. Virtually all Planned Parenthood member-affiliates receive HHS funds and therefore, are subject to the Regulation. For example, 82 of PPFA's affiliates (587 health centers) participate in the Title X family planning program. Even more participate in the Medicaid program. In addition, PPFA affiliates receive other HHS funds that subject them to the Regulation, including under the Social Services Block Grant ("SSBG" or "Title XX") program, 42 U.S.C. § 1397 *et seq.*; the National Breast and Cervical Cancer Early Detection Program ("NBCCEDP"), 42 U.S.C. § 300k *et seq.*; the Infertility Prevention Program ("IPP"), 42 U.S.C. § 247c-1; and the Maternal and Child Health Block Grant ("Title V") program, 42 U.S.C. § 701 *et seq.*

13. These Planned Parenthood member-affiliates reasonably fear that if they continue to hire staff that they are confident will provide comprehensive health services, and if they in fact continue to provide comprehensive health services to the women and men they serve, they may run afoul of the Regulation, thus putting millions of dollars of federal funding at risk. They also reasonably fear that the Regulation threatens the health of the women and men they serve.

14. PPFA sues on its own behalf, on behalf of its member-affiliates that receive federal funds that subject them to the Regulation, on behalf of all current and future member-affiliate employees, staff, servants, officers, and agents, and on behalf of the patients of Planned Parenthood member-affiliates nationwide.

15. Plaintiff PPC is a not-for-profit Connecticut corporation with headquarters in New Haven and a member-affiliate of PPFA. It provides clinical, educational, and counseling services to men and women at 18 health care centers in the state of Connecticut. It is the largest reproductive health care provider in Connecticut, serving more than 61,000 women and men annually. PPC provides a wide range of reproductive health services at all of its health care centers, including: pregnancy diagnosis and counseling; contraceptive counseling; provision of all methods of contraception, including emergency contraception; HIV/AIDS testing and counseling; testing, diagnosis, and treatment of sexually transmitted infections; and cancer screening for cervical and breast cancer. PPC also provides abortion services through 15 weeks, 6 days from the first day of the woman's last menstrual period. Surgical abortion services are available at four of its health centers, and medication abortion is available at those sites as well as at 10 other health centers.

16. PPC participates in many federal programs administered by HHS that subject it to the Regulation, including the Title X program, Medicaid, the SSBG program, the IPP, and the NBCCEDP. PPC is the grantee for the state of Connecticut in the Title X program and is also a grantee in the NBCCEDP, so it is responsible not only for its compliance with the Regulation, but also the compliance of its delegate agencies (or sub-recipients).

17. PPC and its employees, staff, servants, and agents reasonably fear that if they continue to hire staff that they are confident will provide comprehensive health services, and if they in fact continue to provide comprehensive health services to the women and men they serve, they may run afoul of the Regulation, thus putting several millions of dollars of federal funding at risk. They also reasonably fear that the Regulation threatens the health of the women and men they serve.

18. PPC sues on its own behalf, on behalf of all current and future employees, staff, servants, officers, and agents, and on behalf of its patients.

B. Defendant

19. Defendant Michael O. Leavitt is the Secretary of HHS, the agency that promulgated the Regulation. HHS is also responsible for its enforcement. Defendant Leavitt is sued in his official capacity, as are his successors.

IV. THE UNDERLYING STATUTES

20. The Regulation purports to "implement[] and enforce[]" three "federal nondiscrimination statutes" regarding the provision of abortion services – the Church Amendments, the Coats Amendment, and the Weldon Amendment. *See* 45 C.F.R. § 88.1.

A. The Church Amendments, 42 U.S.C. § 300a-7 ("Church")

1. Church (b) and (c)(1)

21. Church (b) and (c)(1) were enacted in 1973 in response to public debate about whether the receipt of federal funds required the provision of abortion or sterilization services.

22. Church (b) states that "[t]he receipt of any grant, contract, loan, or loan guarantee under the Public Health Service Act [42 U.S.C. § 201 *et seq.*], the Community Mental Health Centers Act [42 U.S.C. § 2689 *et seq.*], or the Developmental Disabilities Services and Facilities Construction Act [42 U.S.C. § 6000 *et seq.*]" does not authorize a public official or authority to require anyone to perform or assist in the performance of any abortion or sterilization procedure if it is contrary to his or her religious beliefs or moral convictions or to require an entity to make its facilities available for abortion or sterilization procedures. *See* 42 U.S.C. § 300a-7(b).

23. Church (c)(1) provides that entities that receive those federal funds enumerated in Church (b) may not discriminate against health care personnel based on their decision whether or not to participate in abortion or sterilization procedures. *See* 42 U.S.C. § 300a-7(c)(1).

2. Church (c)(2) and (d)

24. Church Amendments (c)(2) and (d) were added in 1974 when the Senate was considering the National Research Act, which was aimed at funding biomedical and behavioral research, and ensuring that research projects involving human subjects were performed in an ethical manner. *See* 119 Cong. Rec. 29217 (1973).

25. Church (c)(2) states that entities that receive biomedical or behavioral research funds from HHS may not discriminate against an individual because he or she performed or assisted – or refused to perform or assist – in "any lawful heath service or research activity" because it was "contrary to his religious beliefs and moral convictions." 42 U.S.C. § 300a-7(c)(2).

26. Church (d) provides that:

> No individual shall be required to perform or assist in the performance of any part of a health service program or research activity funded in whole or in part under a program administered by [HHS] if . . . contrary to his religious beliefs or moral convictions.

42 U.S.C. § 300a-7(d).

3. Church (e)

27. Church (e) was enacted in 1979, and provides that entities that receive any grant, contract, loan, loan guarantee, or interest subsidy under the Public Health Service Act (42 U.S.C. § 201 *et seq.*), the Community Mental Health Centers Act (42 U.S.C. § 2689 *et seq.*), or the Developmental Disabilities Assistance and Bill of Rights Act of 2000 (42 U.S.C. § 15001 *et seq.*) may not deny admission or otherwise discriminate against applicants for training or study

based on their participation or lack of participation in abortions or sterilizations. *See* 42 U.S.C. § 300a-7(e).

28. The substance of the Church Amendments has remained unchanged since 1979. HHS has never issued any rules or guidance interpreting or implementing these Amendments.

B. The Coats Amendment

29. The Coats Amendment was enacted in 1996 in response to the Accreditation Council on Graduate Medical Education's ("ACGME") guidelines on abortion training. Those guidelines, adopted in July 1995, required that all obstetrics and gynecology residency programs provide induced abortion training beginning January 1, 1996; however, "[n]o program or resident with a religious or moral objection [would] be required to provide training in or to perform induced abortions." National Abortion Federation, Training Opportunities/Residents, http://www.prochoice.org/education/resources/residents.html (last visited Jan. 12, 2009).

30. The Coats Amendment prohibits the federal government, or any state or local government that receives federal financial assistance, from discriminating against any "health care entity" on the basis that

> (1) the entity refuses to undergo training in the performance of induced abortions, to require or provide such training, to perform such abortions, or to provide referrals for such training or such abortions; (2) the entity refuses to make arrangements for any of the activities specified in paragraph (1); or (3) the entity attends (or attended) a post-graduate physician training program, or any other program of training in the health professions, that does not (or did not) perform induced abortions or require, provide or refer for training in the performance of induced abortions, or make arrangements for the provision of such training.

42 U.S.C. § 238n(a).

31. The Coats Amendment provides that "[t]he term 'health care entity' includes an individual physician, a postgraduate physician training program, and a participant in a program of training in the health professions." 42 U.S.C. § 238n(c)(2).

32. Following its enactment in 1996, HHS has never issued any rules or guidance regarding the Coats Amendment.

C. The Weldon Amendment

33. The Weldon Amendment was added to the appropriations bill for the Departments of Labor, Health and Human Services, and Education in 2004 (to the appropriation for fiscal year 2005). Pub. L. No. 108-447, § 508(d), 118 Stat. 2809 (2004). It has been added to each subsequent appropriations act and provides that none of the funds appropriated by those three agencies:

> may be made available to a Federal agency or program, or to a State or local government, if such agency, program, or government subjects any institutional or individual health care entity to discrimination on the basis that the health care entity does not provide, pay for, provide coverage of, or refer for abortions. . . In this subsection, the term "health care entity" includes an individual physician or other health care professional, a hospital, a provider-sponsored organization, a health maintenance organization, a health insurance plan, or any other kind of health care facility, organization, or plan.

Consolidated Appropriations Act 2008, Pub. L. No. 110-161, § 508(d), 121 Stat. 1844, 2209 (2007).

34. The Weldon Amendment similarly has never before been the subject of any guidance or regulation by HHS.

V. THE PROMULGATION OF THE REGULATION

35. In July 2008, The New York Times obtained a draft of the proposed regulation, and reported on it. *See* Robert Pear, *Abortion Proposal Sets Condition on Aid*, N.Y. Times, July 15, 2008, available at http://www.nytimes.com/2008/07/15/washington/15rule.html; *see also* Cristina Page, *HHS Moves to Define Contraception as Abortion*, RH Reality Check, July 15, 2008, http://www.rhrealitycheck.org/blog/2008/07/15/hhs-moves-define-contraception-abortion (providing a link to the full text of the Draft Regulation). A copy of the Draft Regulation is attached hereto as Exhibit B.

36. The Draft Regulation stated that part of the "problem" it was seeking to rectify was that certain state laws require that employee prescription drug benefits include contraception, retail pharmacies dispense contraception, and hospitals provide emergency contraception to rape survivors. *See* Draft Regulation at 8-9.

37. The Draft Regulation defined "abortion" as "any of the various procedures – including the prescription, dispensing, and administration of any drug or the performance of any procedure or any other action – that results in the termination of the life of a human being in utero between conception and natural birth, *whether before or after implantation.*" Draft Regulation at 17 (emphasis added).

38. This definition could reach a range of hormonal drugs as well as some non-hormonal devices that have been approved by the FDA to prevent pregnancy. These drugs and devices are contraceptives because they prevent a pregnancy from establishing by a variety of mechanisms of action, all of which occur prior to implantation. Because implantation is generally recognized as the beginning of pregnancy, regardless of which mechanism of action works in any given case, these drugs or devices always prevent rather than terminate a pregnancy; hence, they are contraceptives.

39. Medication abortion is the use of medications after a pregnancy has been established (*i.e.*, after implantation) to terminate the pregnancy (most frequently the medication is mifepristone – commonly known as RU-486). Medication abortion is different from emergency contraception which is a contraceptive method that works before implantation, and does not disrupt pregnancy. *See Plan B: Questions and Answers*, U.S. Food & Drug Administration (August 24, 2006, updated December 14, 2006), *available at* http://www.fda.gov/CDER/DRUG/infopage/planB/planBQandA20060824.htm (announcing the

approval of the emergency contraceptive drug Plan B as an over-the-counter option, which "can reduce the chances of a woman becoming pregnant").

40. The far-reaching definition of "abortion" in the Draft Regulation to include contraception engendered widespread concern. *See, e.g.*, Stephanie Simon, *Treating the Pill as Abortion, Draft Regulation Stirs Debate*, Wall St. J., Jul. 31, 2008; Editorial, *Bush's latest: Birth control pills are abortion: Proposed rule at HHS would broaden definition of 'abortion,'* Charlotte Observer, July 21, 2008; Editorial, *An anti-abortion ploy disguised as an employment-discrimination imitative, the Bush administration's proposed funding rule would limit women's reproductive health rights*, Seattle Times, July 23, 2008; Editorial, *Redefining abortion: Federal officials considering a rule allowing health care workers to refuse to provide contraceptives*, Houston Chron., Aug. 11, 2008.

41. On August 26, 2008, the Proposed Regulation was published in the Federal Register, giving the public only thirty days to submit comments. 73 Fed. Reg. 50,274-01. The Proposed Regulation, while purporting to clarify the underlying statutes that had been on the books for years without any recognized need for clarification, in fact created significant confusion by defining some of the statutory terms more broadly than their plain meaning could bear, by extending the reach of some of the statutory provisions to those to whom, and under circumstances to which, they were not intended to apply, and by failing to define some of the most critical terms in the underlying statutes. Notably, for example, the Proposed Regulation left the term "abortion" undefined.

42. HHS received approximately 200,000 comments, the overwhelming majority of which were opposed to the Regulation.

43. On December 19, 2008, thirty-two days before President Bush's last day in office, HHS published the Final Regulation, which in almost all respects is the same as the Proposed Regulation. The Regulation is effective on January 20, 2009.

44. The Regulation imposes a new requirement on approximately 572,000 individuals and entities that receive certain federal funds, including funds appropriated by HHS, that those individuals and entities certify to HHS their compliance with the three underlying statutes, as interpreted by HHS. *See* 45 C.F.R. § 88.5.

45. Failure of a regulated entity to comply with the Regulation could lead to termination of all HHS funding as well as return of previous HHS funds. *See* 73 Fed. Reg. 78,074.

VI. COMMENTERS RAISED MANY SIGNIFICANT CONCERNS ABOUT THE REGULATION TO WHICH HHS FAILED TO RESPOND ADEQUATELY

46. The thousands of comments submitted to HHS raised a myriad of concerns about the Regulation. As set forth below, HHS failed to respond to some of the significant issues raised by commenters. Its response to other significant comments was inadequate and creates confusion for the regulated entities. Among the comments to which HHS failed to provide an adequate response, in violation of the APA, are these:

A. The Meaning of "Abortion"

47. Thousands of individuals and organizations – including the American Medical Association, the American College of Obstetricians and Gynecologists, and the American Nurses Association, as well as Plaintiffs – commented that the final rule should include a definition of abortion, clarifying that contraception is not abortion within the meaning of the Rule. These concerns were particularly appropriate in light of the wide reporting about the Draft Regulation, which defined abortion to reach certain forms of contraception.

48. HHS noted this issue in its response to the comments published with the final Regulation, but stated that it "declines to add a definition of abortion to the rule," admitting, however, that "such questions over the nature of abortion and the ending of a life are highly controversial and strongly debated." 73 Fed. Reg. 78,077.

B. Preemption of State Laws

49. Many commenters – including state attorneys general and executives – raised concerns about how the Regulation impacts the ability of states to enforce their own laws that provide women access to health care services, including contraception. For example, commenters asked about the impact of the Regulation on laws such as those that require hospital emergency rooms to provide emergency contraception to rape survivors, require insurers to include contraceptives in their prescription drug benefits, and require pharmacies to dispense all validly prescribed drugs and devices. As with the concerns about the definition of "abortion," these concerns were particularly appropriate given the statement in the Draft Regulation that such state laws were part of the "problem" to which the Regulation was addressed. *See* Draft Regulation at 7-10.

50. In its response to the comments published with the final Regulation, HHS acknowledged that states would have problems enforcing their laws: "While the Department is aware that some States may have laws that, if enforced, depending on the factual circumstances, might violate these federally protected rights, the Department is not aware of any particular instance where a State has done so in an inappropriate fashion." 73 Fed. Reg. 78,088. However, HHS provided no further guidance about future enforcement of state laws either in its response to the comments, or in the Regulation.

C. Operation of the Regulation in Medical Emergency Situations

51. Numerous commenters suggested that HHS clarify that the Regulation does not apply in medical emergencies. For example, commenters asked HHS to clarify whether the Emergency Medical Treatment and Active Labor Act ("EMTALA"), 42 U.S.C. § 1395dd, or state laws that require emergency treatment, could still be enforced in circumstances where patients are denied emergency medical care based on an asserted violation of conscience.

52. These commenters pointed to federal case law and medical journal articles identifying particular circumstances where individuals and institutions have refused to provide proper medical care to women facing serious medical emergencies based on religious beliefs.

53. In its response to the comments published with the final Regulation, HHS noted some of these comments, but failed to explain how, or if, the Regulation is to be enforced in medical emergency situations. In so doing, the Department ignored the evidence provided by commmenters and concluded, contrary to that evidence, that it "is unaware of any hospital" that "has an objection to performing abortions that are necessary to stabilize the mother." 73 Fed. Reg. 78,087.

D. The Meaning of "Discrimination" in the Regulation

54. Numerous commenters – including the Legal Counsel of the EEOC and two current EEOC Commissioners – pointed out that the Regulation does not define "discrimination." In particular, these commenters noted that the Regulation seemed to conflict with the requirements regarding religious discrimination under Title VII of the Civil Rights Act of 1964, 42 U.S.C. § 2000e(j), and therefore was potentially confusing to the regulated community, and would impose a burden on covered employers, particularly small employers.

55. In its response to the comments published with the final Regulation, HHS responded to these comments by saying that it believes that the "protections" of the Church, Coats, and Weldon Amendments "are distinct from, and extend beyond, those under Title VII." 73 Fed. Reg. 78,085. HHS failed to explain the parameters of these extended protections and failed to provide regulated entities with enough guidance to make employment decisions that do not put them at risk of losing federal funding.

56. However, with respect to accommodation, HHS suggested that, unlike under Title VII, employers must accommodate an employee's belief at all costs, regardless of the hardship to the employer. *See* 73 Fed. Reg. 78,085 ("Where an employer will not accommodate an employee's sincere religious belief or moral conviction, it may cease being eligible for federal funds and lose certain federal funding.").

E. The Impact of the Regulation on the Title X Program

57. Title X of the Public Health Service Act, 42 U.S.C. § 300 *et seq.*, is the federal program that subsidizes the provision of family planning services to low-income people. Under Title X, pregnant women must receive nondirective counseling advising them of all of their options. *See* 42 C.F.R. § 59.5; *see also* Consolidated Appropriations Act, 2008, Pub. L. No. 110-161, 121 Stat. 1844, 2170 (2007) ("all pregnancy counseling shall be nondirective").

58. Numerous commenters asked about how the Regulation impacted the Title X program. In its response to the comments published with the final Regulation, HHS responded only regarding the regulatory requirement, explicitly rejecting it:

> With regards to the Title X program, Commenters are correct that the current regulatory requirement that grantees must provide counseling and referrals for abortion upon request (42 CFR 59.5(a)(5)) is inconsistent with the health care provider conscience protection statutory provisions and this regulation. The Office of Population Affairs, which administers the Title X program, is aware of this conflict with the statutory requirements and, as such, would not enforce this Title X regulatory requirement on objecting grantees or applicants.

73 Fed. Reg. 78,087. HHS did not address the statutory requirement of nondirective counseling at all.

F. Application of the Weldon Amendment to Private Entities and Individuals

59. Under the Regulation "[a]ny entity that receives federal funds appropriated through the appropriations act for [HHS] to implement any part of any federal program" shall not subject a health care entity to "discrimination on the basis that the health care entity does not provide, pay for, provide coverage of, or refer for abortion, as part of the federal program for which it receives funding." 45 C.F.R. §§ 88.3(c), 88.4(b)(2).

60. "Entity" is defined to include "an individual physician or other health care professional, health care personnel, a participant in a program of training in the health professions, an applicant for training or study in the health professions, a post graduate physician training program, a hospital, a provider-sponsored organization, a health maintenance organization, a health insurance plan, laboratory or any other kind of health care organization or facility." 45 C.F.R. § 88.2.

61. Section 88.4(b)(2) is plainly an attempt to reflect the restrictions in the Weldon Amendment. But commenters explained that section 88.4(b)(2), which is applicable to private entities and individuals, goes far beyond the Weldon Amendment, because by its terms, Weldon applies only to a "Federal agency or program, or to a State or local government." Pub. L. No. 110-161, § 508(d), 121 Stat. 1844, 2209.

62. In its response to the comments published with the final Regulation, HHS failed to note this significant comment or respond to it in any way.

G. Impermissible Broadening of the Coats Amendment

63. Commenters explained how Section 88.4(a) of the Proposed Regulation impermissibly expanded the Coats Amendment, which is properly limited to discrimination that takes place in the context of abortion training. These commenters cited the language of the Amendment as well as its legislative history in support of their claim.

64. In its response to the comments published with the final Regulation, HHS did not note or respond to this significant comment.

H. Limitless Individual Refusal

65. Under sections 88.3(g)(1) and 88.4(d)(1), any entity "that carries out any part of any health service program or research activity" funded in whole or in part by HHS "[s]hall not require any individual to perform or assist in the performance of any part of a health service program or research activity funded by the Department" if it is contrary to his or her religious or moral beliefs. This is an attempt to reflect the requirements of section (d) of the Church Amendments, 42 U.S.C. § 300a-7(d).

66. Commenters explained that this is a dramatic and inappropriate expansion of Church (d). Plaintiff PPFA pointed to specific legislative history from the adoption of Church (d) which demonstrates that this provision was intended to apply only to individuals who work for entities that receive grants or contracts for biomedical or behavioral research under programs administered by HHS.

67. In its response to the comments published with the final Regulation, HHS failed to note or respond to this significant concern.

I. The Economic Impact of the Regulation

68. HHS conducted an economic analysis of the Regulation, pursuant to Executive Order 12866, and concluded that "[t]he total quantifiable costs of the regulation are estimated to be $43.6 million each year." 73 Fed. Reg. 78,095. HHS reached this number by calculating only "the incremental costs" of regulated entities completing the new certification and in the case of recipients who have sub-recipients, collecting and maintaining their certifications. *Id.* at 78,094.

69. Commenters explained how HHS's economic analysis severely underestimates the costs regulated entities will incur, especially small entities. These commenters noted that HHS did not even consider the costs associated with regulated entities making sure they are in compliance with the Regulation or making staffing adjustments to accommodate their workforce in response to the Regulation.

70. Other commenters explained how HHS failed to consider the costs on health care consumers as a result of the Regulation, including the costs of being denied access to health care information and services, even in life-threatening situations.

71. In its response to the comments published with the final Regulation, HHS responded to these concerns about the insufficiency of its economic analysis with conflicting statements and ultimately concluded that it "continue[s] to assume that, because together these three federal statutes have been in existence for many years, the incremental indirect costs of certification will be minimal for Department funding recipients." 73 Fed. Reg. 78,095.

72. And with respect to patients' access to vital health care services under the Rule, the Department responded only, without any factual or empirical basis, that "[t]his final rule does not limit patient access to health care . . . ." 73 Fed. Reg. 78,093.

J. False Claims Act Liability

73. In the Proposed Regulation, HHS requested comments about whether the new certification should contain language that it is a "material prerequisite" to the payment of HHS funds. In response, commenters asked HHS about potential liability under the False Claims Act, 31 U.S.C. §§ 3729-3731, for certifying compliance with the Regulation.

74. In its response to the comments published with the final Regulation, HHS noted this question, but failed to answer if it believed there would be such liability, stating only that "The Department does not consider the written certification of compliance to be a material prerequisite to the payment of Department funds any more than in any other similarly worded statute or regulation." 73 Fed. Reg. 78,079.

VII. HHS EXCEEDED ITS AUTHORITY IN PROMULGATING THE REGULATION WHICH IS CONTRARY TO THE UNDERLYING STATUTES

75. None of the underlying statutes – nor any other federal law – delegated authority to HHS that authorizes it to issue the Regulation, which carries the force of law.

76. Even if HHS had the authority to issue the Regulation, it exceeded that authority because the Regulation expands the underlying statutes far beyond their terms and what Congress reasonably intended. Examples of those impermissible expansions follow:

77. To the extent that the provisions of the Regulation related to "abortion" are extended to allow refusals to provide health care services and information related to contraception, it is contrary to law because the term "abortion" as used in the Church, Coats, and Weldon Amendments is unambiguous and cannot reasonably be understood to include contraception.

78. To the extent that the Regulation allows refusal of health care services and/or information in a medical emergency, it is contrary to law.

79. The Regulation is not in accordance with law and HHS exceeded its authority because the Regulation expands the protections against religious discrimination beyond those provided under Title VII of the Civil Rights Act, 42 U.S.C. § 2000e(j).

80. Because the Regulation conflicts with the statutory requirement that women receive nondirective counseling under Title X, it is contrary to law and HHS exceeded its authority.

81. In addition, HHS seems to have overridden its own Title X regulations without any rulemaking that specifically addressed this issue. In fact, the counseling and referral regulation (42 C.F.R. § 59.5) remains the same, while the Provider Conscience Regulation, on its face, says nothing about the Title X program. HHS exceeded its authority in changing this requirement in this fashion.

82. HHS also exceeded its authority by expanding the Weldon Amendment, which by its terms applies only to a "Federal agency or program, or to a State or local government," Pub. L. No. 110-161, § 508(d), 121 Stat. 1844, 2209, to apply to private entities and individuals who receive federal funds appropriated by HHS.

83. HHS impermissibly expanded the Coats Amendment, which is properly limited to "discrimination" that occurs in the context of abortion training.

84. By applying Church (d) to any entity "that carries out any part of any health service program or research activity funded in whole or in part" by HHS (45 C.F.R. §§ 88.3(g)(1), 88.4(d)(1)) and broadly defining "individual," "workforce," and "assist in the performance of," HHS has exceeded its authority.

VIII. HHS'S INADEQUATE ECONOMIC ANALYSIS WAS ARBITRARY AND CAPRICIOUS AND IN VIOLATION OF FEDERAL LAW

85. The Regulatory Flexibility Act ("RFA") requires federal agencies promulgating rules to assess the potential impact of the rule on small entities by conducting a regulatory flexibility analysis unless "the head of the agency certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities." 5 U.S.C. §§ 604, 605(b). The certification must be published in the notice of final rulemaking, "along with a statement providing the factual basis for such certification." 5 U.S.C. § 605(b).

86. The Regulation applies to a substantial number of small entities, including PPFA member-affiliates. Yet HHS, without providing any factual basis, certified that the Regulation "will not result in a significant impact on a substantial number of small entities." 73 Fed. Reg. 78,095.

87. It is unclear whether HHS considered the economic impact on small entities at all. To the extent that HHS relied on the insufficient economic analysis it performed pursuant to Executive Order 12866 when it certified that the Regulation will not impose significant costs on small entities, HHS failed to comply with the RFA. The Department also failed to provide a factual basis for its certification.

88. The Congressional Review Act ("CRA"), 5 U.S.C. § 801 *et seq.*, requires that federal agencies submit final rules to Congress. Under the CRA, a "major rule" may not be enforced until sixty calendar days after the rule has been both published in the Federal Register and submitted to Congress. 5 U.S.C. § 801(a)(3)(A). Major rules are those that are determined by the Office of Information and Regulatory Affairs ("OIRA"), in the Office of Management and Budget, to have "an annual effect on the economy of $100,000,000 or more." 5 U.S.C. § 804.

89. Because HHS unreasonably underestimated the costs of the Regulation, it was not classified as major. However, a proper economic analysis would have reached the conclusion that the annual effect of the Regulation on the economy well exceeds $100 million. Thus, it should have been classified as "major," and unenforceable prior to February 17, 2009.

IX. THE EFFECTS OF THE REGULATION

A. Effect on Access to Abortion and Other Medical Services

90. As discussed above, the Regulation allows a broadly defined group of individuals and entities to refuse to provide health care services and information, even perhaps in emergency situations. Under many provisions of the Regulation, the refusal to provide these services need not have a religious or moral basis. *See, e.g.*, 45 C.F.R. §§ 88.4(a), 88.4(b).

91. Pregnant women who are in the process of a miscarriage or are suffering other serious pregnancy-related conditions for which the standard treatment is immediate pregnancy termination, or who have had abortions where there is a complication could now find themselves at a hospital where either the institution or the provider they are assigned to may refuse to provide them with the emergency care they need because they object to participating in the termination of a pregnancy, thus jeopardizing women's lives, health, and future fertility.

92. Women who seek family planning services at federally-funded Title X clinics may no longer be assured that they will receive counseling on all pregnancy options. Nor will they necessarily be guaranteed that they can obtain a referral for an abortion if they request one.

93. Given HHS's purposeful obfuscation of what constitutes "abortion," some women will inevitably be denied access to family planning services and information, including birth control pills, IUDs, and emergency contraception, any of which could (erroneously) be understood as terminating rather than preventing a pregnancy.

94. States may be unable to ensure that their citizens receive access to family planning services. For example, Connecticut, like other states, has attempted to ensure that sexual assault survivors have access to emergency contraception, but following the Regulation, it may be unable to enforce its mandate because some hospitals or individual providers may view emergency contraception as "abortion." The result is that rape survivors will suffer, not only by being put at risk of unintended pregnancy, but also by potentially being denied full information about how to avoid this tragic result.

95. Connecticut, like many other states, also has a law that requires group health insurance plans sold in the state to provide coverage for contraceptive drugs and devices if the plan provides prescription drug coverage. Because the refusals allowed by the Rule are so broad, health insurance plans may refuse to provide this coverage. And they may refuse to do so for any reason – even a financial one – with impunity.

96. The expansive individual refusal provision, 45 C.F.R. § 88.4(d)(1), permits the denial of *any* health care services and information, which will inevitably extend to a wide range of services, including end-of-life care, HIV/AIDS treatment, and mental health services, that are not limited to women and reproductive health care. The Regulation allows any employee, volunteer, or trainee of a health care provider to refuse to treat any patient if doing so would violate his or her religious beliefs or moral convictions, without any concern for the needs of the patient and regardless of what type of health service the patient needs – whether it be contraception, a blood transfusion, condoms to prevent HIV transmission, or mere information about health care options.

B. Impact on Plaintiffs and Their Patients

97. While abortion is a very safe medical procedure, a small percentage of abortion patients at PPFA member-affiliates' clinics will seek follow-up care at hospitals, and member-affiliates rely on the availability of emergency hospital services in the rare event of a complication. If the Regulation takes effect, these patients may, in fact, be denied necessary care. For some of these women, the denial of emergency care could threaten their lives, health, or future fertility.

98. Those PPFA member-affiliates, like PPC, who are Title X grantees may be unable to require their delegate agencies to provide any services related to "abortion," including providing certain methods of contraception, abortion counseling, and abortion referrals. Because the Title X statute requires the provision of a full range of family planning services as well as the provision of nondirective counseling, these member-affiliates may have to decide between complying with the Regulation and complying with the requirements of the Title X program.

99. Moreover, Plaintiffs may lose good will with clients because they may not even know that staff members are not providing information about abortion or contraceptive services, as HHS refused to place any obligation on individuals who object to providing services to notify their employers – or the patient – of their refusal.

100. All PPFA member-affiliates subject to the Regulation will face serious questions about how to conduct their employment practices. Combined, PPFA member-affiliates employ almost 11,500 individuals nationwide, including more than 9,000 full-time employees. In addition, PPFA member-affiliates have close to 20,000 volunteers. In any given year, PPFA member-affiliates make at least 1,000 new hires nationwide.

101. Because of the confusion created by the Regulation's failure to define "abortion" and "discrimination," Plaintiffs may have to hire or accommodate individuals who refuse to provide – or even give information about – the services that are at the core of Planned Parenthood's mission, including contraception and abortion.

102. Many PPFA member-affiliates have very few staff members at any particular health center at a time. For example, Planned Parenthood of Southwest Ohio has nine clinics at which there is typically only one licensed clinician at any given time. These clinicians are expected to provide a range of reproductive health care services that only licensed clinicians can provide, including prescription contraception, emergency contraception for minors, and screening and treatment for sexually transmitted infections. Plaintiff PPC has five clinic sites where there is only one licensed clinician at any given time, who is expected to provide a full range of reproductive health care, including contraception, emergency contraception, and medication abortion. PPFA member-affiliates could be forced to hire or accommodate individuals in these jobs who refuse to provide these services. Such accommodation would be very expensive, time-consuming, and in certain circumstances, impossible.

103. In addition, given HHS's statements that these Regulations are more protective of employees who refuse to perform job functions than Title VII, Plaintiffs will have to spend significant staff time revising all employment materials, conducting trainings with human resources personnel and supervisors, and perhaps retaining and paying outside legal counsel. However, given HHS's unclear and incomplete statements on these issues, Plaintiffs do not know exactly *how* to change their policies to avoid running afoul of the Regulation.

104. The lack of clarity about these issues places Plaintiffs at risk of losing tens of millions of dollars of federal funds if they continue to strive to provide a full range of

reproductive health care services to the women and men who depend on them. Many of Plaintiffs' member-affiliates would have to consider reducing their hours, their staff, or even closing health centers if they lost all of their HHS funding.

105. Plaintiffs may also have to defend "whistleblower" lawsuits under the False Claims Act, 31 U.S.C. §§ 3729-3731, which provides that any person who:

> knowingly presents, or causes to be presented, to an officer or employee of the United States Government . . . a false or fraudulent claim for payment or approval; [or] knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government; . . . is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, plus 3 times the amount of damages which the Government sustains because of the act of that person.

31 U.S.C. § 3729(a). Civil actions for violations of 31 U.S.C. § 3729, may be brought by the U.S. Government or private persons. *See* 31 U.S.C. § 3730(a) and (b).

X. INJUNCTIVE RELIEF

106. Plaintiffs have no adequate remedy at law and will suffer irreparable harm for continued violations of their and their patients' rights if the Regulation is enforced.

107. As outlined above, enforcement of the Regulation will cause irreparable harm by threatening Plaintiffs' patients' ability to receive the care they need, even in emergency situations. It will also threaten Plaintiffs' ability to fulfill their mission and provide a full range of reproductive health care services.

108. HHS has failed to provide Plaintiffs with clear notice of the conduct that will save them from losing huge sums of federal funding and facing whistleblower lawsuits. Plaintiffs are, therefore, impermissibly subject to arbitrary and discriminatory enforcement of the Regulation.

109. The Regulation also threatens Plaintiffs' First Amendment rights by requiring them to accommodate all religious objections by employees.

XI. CLAIMS FOR RELIEF

First Count

110. Plaintiffs hereby incorporate by reference Paragraphs 1 through 109 above.

111. HHS's rulemaking was arbitrary, capricious, an abuse of discretion, and without observance of procedure required by law, in violation of the Administrative Procedure Act, 5 U.S.C. § 706(2), because HHS failed to respond adequately to significant comments about numerous issues, including:

a. The meaning of "abortion;"

b. How the Regulation intersects with state laws;

c. The operation of the Regulation in medical emergency situations;

d. The meaning of "discrimination;"

e. The conflict between the Regulation and the Title X statutory requirement of nondirective counseling;

f. The overly broad reach of the Regulation, including its expansion of the Weldon Amendment to private entities and individuals, the expansion of the Coats Amendment beyond abortion training, and the expansion of Church (d) beyond biomedical or behavioral research;

g. The economic impact of the Regulation; and

h. Liability under the False Claims Act.

Second Count

112. Plaintiffs hereby incorporate by reference Paragraphs 1 through 111 above.

113. The Regulation is arbitrary, capricious, an abuse of discretion, not in accordance with law, in excess of statutory authority, and without observance of procedure required by law,

in violation of the Administrative Procedure Act, 5 U.S.C. § 706(2), in at least the following respects:

a. None of the underlying statutes or any other federal law delegated authority to HHS to issue the Regulation;

b. The term "abortion" as used in the underlying statutes does not include contraception;

c. The underlying statutes do not preempt the provision of emergency care;

d. The Title X statutes and regulations require the provision of nondirective options counseling;

e. The Weldon Amendment does not reach individuals and private entities;

f. The Coats Amendment does not extend beyond abortion training; and

g. The individual refusal of subsection (d) of the Church Amendment is limited to grants or contracts for biomedical or behavioral research.

Third Count

114. Plaintiffs hereby incorporate by reference Paragraphs 1 through 113 above.

115. In promulgating the Regulation, HHS acted in violation of the Administrative Procedures Act, 5 U.S.C. § 706(2), the Regulatory Flexibility Act, 5 U.S.C. § 601 *et seq.*, the Congressional Review Act, 5 U.S.C. § 801 *et seq.*, and Executive Order 12866 by failing to conduct an adequate cost-benefit analysis, certifying that the Regulation will not have a significant economic impact on a substantial number of small entities; without a factual basis for such certification, and improperly classifying the Regulation as not a major rule.

Fourth Count

116. Plaintiffs hereby incorporate by reference Paragraphs 1 through 115 above.

117. By failing to give adequate notice of the conduct it proscribes, and by encouraging arbitrary enforcement, the Regulation violates the rights of Plaintiffs to due process as guaranteed by the Fifth Amendment to the United States Constitution.

Fifth Count

118. Plaintiffs hereby incorporate by reference Paragraphs 1 through 117 above.

119. By requiring absolute accommodation of employees with religious objections, the Regulation violates Plaintiffs' rights guaranteed by the First Amendment to the United States Constitution.

Sixth Count

120. Plaintiffs hereby incorporate by reference Paragraphs 1 through 119 above.

121. By failing to ensure that women needing abortions to protect their lives and health are able to obtain the care they need, the Regulation violates Plaintiffs' patients' right to privacy and liberty guaranteed by the Due Process Clause of the Fifth Amendment.

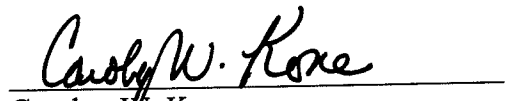
WHEREFORE, Plaintiffs ask this Court:

A. To issue injunctive relief, restraining Defendant, his employees, agents, and successors from enforcing the challenged Regulation;

B. To enter judgment declaring the challenged Regulation to be unlawful; and

C. To grant such other and further relief as this Court should find just and proper, including attorneys' fees and costs.

PLAINTIFFS,
PLANNED PARENTHOOD FEDERATION OF AMERICA, INC. and PLANNED PARENTHOOD OF CONNECTICUT, INC.,



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*Motion for Admission as Visiting Attorney Pending