UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF CONNECTICUT

NATIONAL FAMILY PLANNING & REPRODUCTIVE HEALTH ASSOCIATION, INC. and FAIR HAVEN COMMUNITY HEALTH CLINIC, 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. _____ **COMPLAINT**

I. INTRODUCTION

1. This action, brought under the Administrative Procedure Act, challenges a new United States Department of Health and Human Services regulation that significantly undermines the ability of millions of women and men in this country to access essential family planning and other health care services and information.

2. The regulation, entitled "Ensuring That Department of Health and Human Services Funds Do Not Support Coercive or Discriminatory Policies or Practices in Violation of Federal Law," 73 Fed. Reg. 78,072 (Dec. 19, 2008) (to be codified at 45 C.F.R. Part 88) (the "Regulation"), was promulgated on December 19, 2008, and will become effective on January 20, 2009. A copy of the Regulation is attached as Exhibit A.

3. The Regulation purports to implement and enforce three federal laws – the Church, Coats, and Weldon Amendments – that, in general, provide individuals and institutions certain protections if they refuse to participate in the provision of abortion

and sterilization services. These laws have been on the books for years (and in some cases decades) without the Department of Health and Human Services ("HHS" or "Department") ever seeking to promulgate implementing regulations.

4. On its way out of office, however, the Bush Administration promulgated this midnight Regulation which dramatically expands the reach of these long-standing laws. For example, the Regulation allows health care providers that deny patients access to contraceptive services or to appropriate care in a medical emergency to claim new protections for those refusals. Indeed, it creates new rights for health care providers to deny patients access to *any* health care service to which the provider objects. In addition, the Regulation creates new rights for health care providers that withhold basic information from patients about their treatment options. And the Regulation declines to require that patients even be told their health care provider is withholding information or services. The Regulation also threatens the ability of states to enforce their own laws that promote access to reproductive health care, including laws that require insurance companies to include contraception in their prescription drug benefit plans, that require hospitals to provide emergency contraception to rape survivors, and that require pharmacies to fill prescriptions for birth control.

5. The Regulation's radical expansion of the underlying federal laws is, among other things, contrary to clear statutory language and congressional intent. The Regulation is, therefore, invalid under the Administrative Procedure Act (the "APA").

6. In addition, in its haste to finalize the Regulation before the end of the Bush Administration, HHS failed to comply with basic procedural requirements set forth in the APA. For example, although HHS allowed only thirty days for public comment, it

received more than 200,000 comments, the overwhelming majority of which opposed the Regulation. Commenters, including the American Medical Association, the American Hospital Association, the Association of American Medical Colleges, and numerous Governors and State Attorneys General, raised significant concerns about the Regulation and its effects on patients seeking vital medical care. In addition, the Equal Employment Opportunity Commission ("EEOC"), the federal agency charged with enforcing federal prohibitions against religious discrimination in employment, commented that the Regulation was unnecessary to protect individual religious liberty and would needlessly upset the current balance between such liberty and the ability of patients to obtain medical care. In violation of its legal obligations under the APA, HHS failed to provide meaningful responses to these significant concerns.

7. The Regulation also violates the constitutional rights of Plaintiff National Family Planning & Reproductive Health Association's members and Plaintiff Fair Haven Community Health Clinic (hereinafter "Plaintiffs"). As an initial matter, because it imposes a categorical requirement that Plaintiffs accommodate the religious objections of their employees, whatever the cost, the Regulation violates the Establishment Clause. In addition, because it subjects Plaintiffs to loss of hundreds of millions of dollars for failure to comply with standards that are entirely unclear, the Regulation is unconstitutionally vague.

8. Plaintiffs, therefore, seek a declaration that the Regulation violates the APA and is unconstitutional, as well as injunctive relief preventing enforcement of the Regulation.

II. JURISDICTION AND VENUE

9. This Court has jurisdiction over the claims alleged in this Complaint pursuant to 5 U.S.C. §§ 701-706 (Administrative Procedure Act), 28 U.S.C. § 1331 (federal question), 28 U.S.C. § 2201 (declaratory relief), and 28 U.S.C. § 2202 (injunctive relief).

10. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(e) because Plaintiff Fair Haven Community Health Clinic's ("FHCHC") headquarters, main clinical site, and five school-based health clinics are located in this district.

III. PARTIES

11. Plaintiff National Family Planning & Reproductive Health Association ("NFPRHA") is the only national professional membership organization dedicated to increasing access to family planning and reproductive health care for low-income and uninsured individuals. NFPRHA has over 154 organizational members located in 46 states and the District of Columbia. These members operate or fund a network of more than 3,700 health centers and service sites that provide family planning services.

12. NFPRHA's members include state, county, and local health departments; family planning councils that receive and distribute federal funds to other health service providers; independent, free-standing family planning clinics; hospital-based clinics; and other private nonprofit family planning organizations and providers.

13. The vast majority of NFPRHA's organizational members, and their network of health centers, receive funds through HHS and are therefore subject to the Regulation. For example, over 85% of NFPRHA's organizational members receive

14. In 2007, nearly 5 million individuals nationwide received family planning services funded through Title X. These services include basic reproductive health exams; contraceptive counseling; all methods of contraception, including birth control pills, emergency contraception, and intra uterine contraceptives (commonly called IUDs); breast and pelvic exams; cervical cancer screening, education on health promotion and disease prevention; pregnancy testing and non-directive pregnancy counseling and referrals; screening for, and treatment of, sexually transmitted infections; and HIV testing and counseling. In addition to providing the full package of Title X services, some NFPRHA members also provide a range of other reproductive and primary health care including pregnancy care and abortion services.

15. The large majority of patients who depend on family planning services funded by Title X live at or below 100% of the poverty line and are uninsured or underinsured.

16. Most of NFPRHA's organizational members also receive Medicaid reimbursement for family planning and other health services provided to patients. Many members also receive other HHS funds that subject them to the Regulation, including, *inter alia*, money from the Title V Maternal and Child Health Block Grant, the Title XX

17. Thus, Title X-funded NFPRHA members, and their network of health centers, receive hundreds of millions of federal dollars to provide comprehensive family planning and related health services to millions of low-income and uninsured or underinsured patients. Access to the health centers and service sites operated and funded by NFPRHA members is critical for these patients as most have no other access to family planning and related services.

18. NFPRHA members reasonably fear that compliance with the Regulation will prevent them from providing the same high-quality, comprehensive reproductive health care that they currently provide to their patients. At the same time, failure to comply with the Regulation will subject NFPRHA members to the loss of hundreds of millions of dollars of federal funding without which they cannot operate. NFPRHA members also reasonably fear that the Regulation will threaten the health of the women they serve by impeding women's access to comprehensive reproductive health services and emergency care.

19. NFPRHA sues on behalf of all current and future members that receive federal funds that subject them to the Regulation; on behalf of those members' sub-grantees, employees, staff, servants, officers, and agents; and on behalf of the patients of NFPRHA members nationwide.

20. Plaintiff Fair Haven Community Health Clinic is a nonprofit, federally recognized community health center located in the Fair Haven section of New Haven, Connecticut. Through its main clinical site and five school-based health clinics, Plaintiff

FHCHC provides comprehensive primary health care services, such as physical examinations, episodic care, and management of chronic problems, to the greater Fair Haven community. In addition, FHCHC provides the full range of family planning services to its patients including pregnancy tests; pregnancy and contraceptive counseling; contraceptive services, including birth control pills, IUDs, and emergency contraception; and HIV testing and services for HIV-positive patients. FHCHC also provides prenatal care to its pregnant patients.

21. Plaintiff FHCHC serves over 13,000 patients annually. Ninety-five percent of FHCHC's patients are below the poverty level and nearly half are uninsured or underinsured. There are essentially no other primary health care providers in the Fair Haven area but FHCHC. In fact, according to the federal government, Fair Haven is a "health professional shortage area," a designation which reflects, *inter alia,* local poverty rates, the low ratio of doctors to the local population, and high infant mortality rates. Thus, without the services provided by FHCHC on a daily basis, the women, men, and families of Fair Haven would suffer a devastating loss.

22. Plaintiff FHCHC is a NFPRHA member.

23. Plaintiff FHCHC receives HHS funds and is therefore subject to the Regulation. For example, FHCHC receives Title X family planning and Medicaid dollars. FHCHC also receives other HHS funds that subject them to the Regulation, such as funding through the Ryan White HIV/AIDS Program and the Women, Infants and Children ("WIC") program. In addition, as a federally qualified health center, Plaintiff FHCHC receives a grant from HHS under Section 330 of the Public Health Services Act.

24. Approximately twenty-five percent of FHCHC's annual budget (approximately 10.5 million dollars) is comprised of federal funds.

25. Plaintiff FHCHC reasonably fears that compliance with the Regulation may place significant barriers in the way of its patients' ability to access essential health care services. Yet, if FHCHC was found to be in violation of the Regulation, it could lose millions in federal funding, causing it to severely curtail its services, and possibly even discontinue services to uninsured patients altogether.

26. Plaintiff FHCHC sues on its own behalf, on behalf of all current and future employees, staff, servants, officers, and agents, and on behalf of its patients.

27. Defendant Michael Leavitt is the Secretary of the Department of Health and Human Services and is responsible for all functions of HHS and its component organizations. HHS promulgated the Regulation that is challenged in this litigation and is also responsible for its enforcement. Defendant Leavitt is sued in his official capacity, as are his successors.

IV. THE UNDERLYING STATUTES

28. The Regulation purports to implement and enforce the Church Amendments, 42 U.S.C. § 300a-7, the Coats Amendment, 42 U.S.C. § 238n, and the Weldon Amendment, Consolidated Appropriations Act, 2008, Pub. L. 110-161, §508(d), 121 Stat. 1844, 2209 (2007).

A. The Church Amendments

29. The Church Amendments refer to a series of laws passed in the early 1970s.

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

30. The first set of these provisions, Church (b) and (c)(1), was passed shortly after the United States Supreme Court's decision in *Roe v. Wade*, 410 U.S. 113 (1973). In the wake of that decision recognizing constitutional protection for the right to choose abortion, some courts held that the receipt of federal funds obligated institutions to provide abortion and/or sterilization services. *See Doe v. Bellin Memorial Hospital*, 479 F.2d 756 (7th Cir. 1973); *Taylor v. St. Vincent's Hospital*, 369 F. Supp. 948 (D. Mont. 1973).

31. In response to those decisions, Congress passed a law to make clear that the receipt of federal funding does not, in and of itself, obligate individuals or entities to provide abortion or sterilization services. *See, e.g.*, 119 Cong. Rec. S9599-S9601 (daily ed. March 27, 1973) (statement of Sen. Church).

32. Subsection (b)(1) of the Church Amendments states that "[t]he receipt of any grant, contract, loan, or loan guarantee under[, *inter alia*,] the Public Health Services Act [42 U.S.C.A. § 201 *et seq.*] by any individual . . . does not authorize any court or other public official to require . . . such individual to perform or assist in the performance of any sterilization procedure or abortion" if it "would be contrary to his religious beliefs or moral convictions." 42 U.S.C. § 300a-7(b)(1).

33. Subsection (b)(2) further provides that the receipt of such funds does not authorize any court or other public official to require a receiving entity to "(A) make its

facilities available for the performance of any sterilization procedure or abortion if the performance of such procedure or abortion in such facilities is prohibited by the entity on the basis of religious beliefs or moral convictions, or (B) provide any personnel for the performance or assistance in the performance of any sterilization procedure or abortion" if it "would be contrary to the religious beliefs or moral convictions of such personnel." 42 U.S.C. § 300a-7(b)(2).

34. Subsection (c)(1) of the Church Amendments prohibits entities that receive funds under, *inter alia*, the Public Health Services Act, from "discriminat[ing] in the employment, promotion, or termination of employment of" or "in the extension of staff or other privileges, of any physician or other health care personnel" because such person:

a. "performed or assisted in the performance of a lawful sterilization procedure or abortion;" or

b. "refused to perform or assist in the performance of such a procedure or abortion" because such procedures are "contrary to his or her religious beliefs or moral convictions."

42 U.S.C. § 300a-7(c)(1).

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

35. Subsections (c)(2) and (d) of the Church Amendments were added in 1974 when the Senate was considering the National Research Act, which dealt with funding for biomedical and behavioral research, and was designed to ensure that research projects involving human subjects were performed in an ethical manner. *See* 119 Cong. Rec. S29213-S29232 (daily ed. Sept. 11, 1973).

36. Subsection (c)(2) prohibits any entity that receives a grant or contract for biomedical or behavioral research under any program administered by the Secretary of Health and Human Services from "discriminat[ing] in the employment, promotion, termination of employment of" or "extension of staff or other privileges to any physician or other health care personnel" because:

a. Such person "performed or assisted in the performance of any lawful health service or research activity;" or

b. Such person "refused to perform or assist in the performance of any such service or activity on the grounds that" it would be "contrary to his or her religious beliefs or moral convictions;" or

c. Because of such person's "religious beliefs or moral convictions respecting any such service or activity."

42 U.S.C. § 300a-7(c)(2).

37. Subsection (d), which was also passed as part of the National Research Act, provides that "[n]o 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 his performance . . . would be contrary to his religious beliefs or moral convictions." 42 U.S.C. § 300a-7(d).

3. Church (e)

38. Subsection (e) of the Church Amendments was enacted in 1979 and provides that entities that receive funds under, *inter alia*, the Public Health Services Act may not deny admission or otherwise discriminate against applicants for training or study based on their participation in abortions or sterilizations. 42 U.S.C. § 300a-7(e).

B. The Coats Amendment

39. In 1996, Congress adopted the Coats Amendment in response to a decision by the Accrediting Council for Graduate Medical Education to require obstetrician-gynecologist residency programs to provide abortion training.

40. The Coats Amendment prohibits the federal government, or any state or local government that receives federal financial assistance, from discriminating against a 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).

C. The Weldon Amendment

41. The Weldon Amendment refers to a rider that has been attached to the Labor, Health, and Human Services, and Education, and Related Agencies Appropriations Act every year since 2004.

42. It provides that none of the funds appropriated in that Act "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." Consolidated Appropriations Act, 2008, Pub. L. 110-161, § 508(d), 121 Stat. 1844, 2209 (2007).

* * *

43. None of the above laws, nor any other federal statute, delegates authority to HHS to promulgate this Regulation. Nor has HHS ever issued any regulations or guidance regarding any of these laws despite the fact that many of these provisions have been on the books for more than three decades.

V. THE DEPARTMENT'S PROMULGATION OF THE REGULATION

44. In July 2008, a draft version of the Regulation was apparently leaked to the press. A copy of the Draft Regulation is attached as Exhibit B.

45. The Draft Regulation stated that "the Problem" it was designed to address was, in large part, state laws that promote access to contraceptive services, including laws that require insurance companies to cover contraceptives on par with other prescription drugs (commonly called contraceptive equity laws), laws that require pharmacies to dispense contraception, and laws that require hospitals to offer emergency contraception to prevent pregnancy. Draft Regulation at 8-10.

46. To "fix" this "problem," the Draft Regulation defined abortion, for purposes of the underlying statutes, 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 a life of a human being in utero between conception and natural birth, *whether before or after implantation*." Draft Regulation at 30 (emphasis added).

47. This definition could encompass some of the most widely used methods for *preventing* pregnancy, such as birth control pills, emergency contraception, and IUDs because these methods may occasionally work by interfering with implantation of a

fertilized egg in the lining of the uterus. (Emergency contraception or EC is essentially a high dose of birth control pills taken shortly after unprotected intercourse to prevent pregnancy.)

48. According to the accepted scientific and medical definitions, pregnancy begins only after implantation of the fertilized egg. Abortion is the termination of an established pregnancy. Neither Congress nor HHS has ever adopted a definition of pregnancy or abortion that deviates from these accepted medical and scientific definitions.

49. The re-definition of abortion in the Draft Regulation became the subject of immediate controversy, sparking a significant public response from elected officials, the scientific, medical, public health and advocacy communities, and the general public. *See, e.g.*, Susan Campbell, *Don't Let Bush Administration Redefine Pregnancy*, HARTFORD COURANT, Aug. 17, 2008; Rob Stein, *Birth Control Fears Addressed*, WASH. POST, Aug. 9, 2008 at A02; Jeffrey Young, *Clinton, Murray Slam Bush Official on Abortion Proposal*, THE HILL, Aug. 8, 2008; Editorial, *Playing Politics with Women's Health Care*, STAR TRIBUNE, Aug. 2, 2008 at 4; Rob Stein, *Proposal Stirs Debate on Rights, Religion*, WASH. POST, July 31, 2008; Jessica Arons, *Contraception is the New Abortion*, SCIENCE PROGRESS, July 28, 2008; Editorial, *An Anti-Abortion Ploy*, SEATTLE TIMES, July 23, 2008 at B10; Deborah Kotz, *A Government Threat to Birth Control*, US NEWS & WORLD REPORT, July 22, 2008.

50. On August 26, 2008, HHS officially published a proposed version of the Regulation in the Federal Register. *See* 73 Fed. Reg. at 50,274.

51. The Proposed Regulation omitted any definition of abortion.

52. However, in statements to the press, Secretary Leavitt suggested that individuals and entities may seek to rely on the Regulation for protection for their refusal to provide contraceptives. *See, e.g.*, Jacob Goldstein, *Feds Move to Protect Health Workers Who Oppose Abortion*, WSJ HEALTH BLOG, Aug. 22, 2008 (quoting Leavitt's statement that "some medical providers may want to [use the Regulation to] 'press the definition' and make the case that some forms of contraception" are equal to an abortion) http://blogs.wsj.com/health/2008/08/22/feds-move-to-protect-health-workers-who-oppose-abortion/; Rob Stein, *Protections Set for Antiabortion Health Workers. Opponents Denounce Proposed Regulation Allowing Federal Officials to Pull Funding*, WASHINGTON POST, Aug. 22, 2008, at A01 (quoting Leavitt's statement that the Regulation "does not seek to resolve any ambiguity" as to whether health care providers may consider birth control pills, emergency contraception, or other forms of contraception to be equivalent to an abortion).

53. On December 19, 2008, HHS issued the Final Regulation. *See* 73 Fed. Reg. 78,072. In some respects, the language of the Regulation looks similar to the language of the underlying statutes. Upon closer inspection, however, the Regulation vastly expands their scope beyond their plain language and beyond congressional intent.

54. The Regulation accomplishes this by expanding the categories of individuals and entities whose refusals to provide information and services are protected; expanding the types of services that individuals and entities are allowed to refuse to provide; and expanding the types of entities that are required to accept such refusals.

55. In addition, despite thousands of comments requesting that it clarify certain applications of the Regulation (for example, whether the Department intends for

the term abortion to be read to include contraception and whether the Regulation's protections for providers who deny services apply in emergencies), HHS fails to provide the requested clarification and, in many instances, the response to the comments only adds to the confusion.

56. Despite this confusion, under the Regulation an estimated 572,000 individuals and entities that receive federal funding or reimbursement for the provision of health care services or research activities are required to certify their compliance with the Regulation. *See* 73 Fed. Reg. at 78,072, 78,094.

57. Failure to comply with the Regulation subjects regulated entities, including Plaintiffs, to the loss of federal funds as well as claims for return of previously paid HHS funds.

VI. THE DEPARTMENT'S FAILURE TO RESPOND TO SIGNIFICANT COMMENTS

58. Despite the fact that the underlying laws have been on the books for years, and in some cases decades, without the need for HHS regulations, when the Department proposed the Regulation it gave the public only 30 days to submit comments, the minimum period required by law.

59. Even in that short time, over 200,000 comments were submitted, the vast majority of which opposed the Proposed Regulation.

60. Comments opposing the Proposed Regulation were submitted, by numerous organizations and individuals, including:

a. Medical professional associations, such as the American Medical Association, the American Hospital Association, the American

Association of Medical Colleges, the American College of Obstetricians and Gynecologists, the American Academy of Pediatrics, the American Psychiatric Association, and the National Association of Children's Hospitals;

b. The EEOC;

c. State officials, including at least 14 State Attorneys General and seven Governors;

d. Associations of state health officials, such as the Association and Territorial Aids Directors and the National Association of County and City Health Officials, as well as numerous state public health departments;

e. Federal officials, including at least 28 U.S. Senators (including President-elect Barack Obama and Vice President-elect Joe Biden) and numerous members of the House of Representatives; and

f. Religious groups, such as the Unitarian Universalist Association of Congregations, the United Methodist Church, Catholics for Choice and the Religious Action Center of Reform Judaism.

61. These comments highlighted numerous ways in which the Proposed Regulation would drastically expand the reach of the underlying federal statutes; impede patients' access to reproductive health care services and other vital medical care, including emergency care; create conflict with existing federal and state laws; and foster confusion for entities covered by the Regulation.

62. As detailed below, HHS failed to meaningfully address numerous significant comments, and indeed, in some cases failed to address such comments at all. On December 19, 2008, the Department published the Final Regulation which was, by and large, unchanged from the Proposed Regulation.

A. Whether the Regulation Protects Refusals to Provide Contraceptive Services

63. Thousands of commenters, including leading medical groups such as the American Medical Association and the American College of Obstetricians and Gynecologists, asked the Department to clarify that the term "abortion," as used in the Regulation, does not include contraception. Commenters pointed out that the definition in the Draft Regulation was contrary to the accepted medical and scientific definitions and in conflict with other provisions of federal law. They highlighted the confusion engendered by the Draft Regulation and Defendant Leavitt's subsequent statements.

64. In response, HHS stated "such questions over the nature of abortion and the ending of a life are highly controversial and strongly debated," 73 Fed. Reg. at 78,077, but refused to provide any clarification about how it intended to interpret the Regulation.

B. Preemption of State Laws that Protect Access to Contraceptives

65. Similarly, a significant number of commenters, including numerous state officials, raised concerns that, particularly without clarification regarding HHS's use of the term abortion, the Regulation could affect the ability of states to enforce their own laws, particularly those laws that promote access to contraceptive services.

66. For example, these commenters raised concerns that the Regulation could interfere with states' abilities to enforce their contraceptive equity laws, laws requiring

that hospitals provide emergency contraception to rape survivors, and laws requiring pharmacies to fill prescriptions for contraception. These commenters noted that the stated purpose of the Draft Regulation was to prevent states from enforcing such laws.

67. Again, HHS provided no clear response to these comments. Rather, it simply stated that 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." *Id.* at 78,088. HHS cautioned, however, that states should avoid enforcing their laws in this unclarified "inappropriate" fashion "or risk the loss of federal funds." *Id.*

C. Conflict with Title X

68. A large number of commenters highlighted the conflict between the Proposed Regulation and the requirements of Title X. In particular, these comments centered on statutory and regulatory requirements that all pregnancy counseling provided by Title X recipients be non-directive and therefore offer women information about all of their options while pregnant, including abortion. *See* Consolidated Appropriations Act, 2008, Pub. L. No. 110-161, 121 Stat. 1844, 2170 (2007) ("all pregnancy counseling shall be non-directive"); 42 C.F.R. § 59.5 (2008).

69. HHS acknowledged that the Regulation was in conflict with the Title X regulation requiring non-directive options counseling, and stated that the Title X regulation requiring such non-directive counseling would not be enforced. 73 Fed. Reg. at 78,087. HHS, however, did not address the Regulation's conflict with the statutory

requirement nor provide any guidance about how regulated entities are to deal with these conflicting mandates.

D. The Regulation's Application in Emergency Circumstances

70. Numerous comments also raised serious concerns about whether the Proposed Regulation applied in emergency circumstances where health care professionals or institutions refuse to provide care urgently needed to protect a patient from serious risks to her health or life.

71. Commenters pointed to specific examples where patients facing serious medical emergencies have been denied proper medical care because of an institution's or individual's objection to the provision of the necessary care.

72. In addition, commenters raised questions about the Proposed Regulation's interaction with the Emergency Medical Treatment and Active Labor Act, 42 U.S.C. § 1395dd ("EMTALA"), and similar state laws, which require hospitals with emergency rooms to provide appropriate care to patients in emergencies.

73. The Department did not respond to the comments asking whether the Regulation applied in emergencies.

74. With respect to the enforcement of laws requiring the provision of appropriate care in medical emergencies, the Department refused to state that these laws may be enforced. Instead it merely stated, contrary to the evidence before it, that it knew of no hospital with objections to performing abortions that are necessary to stabilize the mother as that term has been interpreted in the context of EMTALA, and that it therefore did not anticipate any conflict between the Regulation and EMTALA. 73 Fed. Reg. at 78,087.

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

75. Commenters also objected to the fact that section 88.3(c) of the Proposed Regulation extended the restrictions of the Weldon Amendment, as reiterated in section 88.4(b)(2) of the Proposed Regulation, to apply to individuals and private entities. *See* 73 Fed. Reg. at 50,283. These commenters stated that such an extension was contrary to both the plain language of the Weldon Amendment – which restricts only the actions of "Federal agenc[ies] or program[s]" or "State or local government[s]" – and to congressional intent.

76. The Department provided no response to these comments and made no change from the Proposed Regulation.

F. The Meaning of the Term "Discrimination" and the Requirement to Accommodate Refusals

77. The Legal Counsel of the EEOC, on behalf of the Commission, as well as two current Commissioners, also submitted comments objecting to the Proposed Regulation. They noted that the Regulation was "unnecessary to protect the religious freedom and freedom of conscience of health care workers because Title VII [of the Civil Rights Act of 1964] already serves that purpose." Commissioners Letter at 2; *see also* EEOC Letter at 2. Along with many other commenters, the EEOC charged that the Proposed Regulation threatened to upset the careful balance between protection for employees' religious beliefs and employers' ability to ensure good care for their patients that has existed under Title VII for more than forty years. The EEOC also commented that by introducing a new standard, the Regulation would disrupt a judicially-approved

balance, "create confusion for employers, who would still be subject to the Title VII standard," and "impose a burden on covered employers." EEOC Letter at 2, 4.

78. In response, the Department acknowledged that it intended the Regulation to provide "protections that are distinct from, and extend beyond, those under Title VII," 73 Fed. Reg. at 78,085, but failed to give any response to the criticisms that such an extension was unnecessary and would have a detrimental effect on health care employers' ability to treat their patients. Nor did HHS adequately respond to the criticism about the confusion this new standard would create by supplying sufficient guidance to regulated entities about what employment actions will cause them to jeopardize their federal funding.

G. The Meaning of "Assist in the Performance"

79. Commenters also complained that the Proposed Regulation's expansive definition of the term "assist in the performance" created a new right for individuals to refuse to provide information and counseling to patients, even though legal and ethical principles of informed consent require health care professionals to ensure that patients receive information about all treatment options, including those to which the provider objects or does not provide.

80. Although the Department conceded that "informed consent is crucial to the provision of quality health care services," 73 Fed. Reg. at 78,082, the Department suggested only that patients make "informed decisions," *id.*, about their choice of health care provider. This response completely disregards the fact that the millions of Americans who rely on health care funded by the Department have few, if any, choices about who their health care provider will be. Moreover, the Department refused to

require providers to inform patients that they will not provide certain information or services, *see id.* at 78,084, so even patients with means will have no way to make an informed selection among health care providers.

H. The Economic Impact of the Regulation

81. HHS conducted an economic analysis of the Regulation, pursuant to Executive Order 12866, and concluded that "the total quantifiable costs of the regulation are estimated to be $43.6 million each year." 73 Fed. Reg. at 78,095. This figure includes only HHS's estimate of "the incremental costs" of requiring regulated entities to file a form certifying compliance with the Regulation, and in the case of recipients who have sub-recipients, collecting and maintaining their certifications. *Id.* at 78,094.

82. 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 revising policies and procedures and training staff to comply with the Regulation or of making staffing adjustments to accommodate their workforce in response to the Regulation.

83. Other commenters explained how HHS failed to consider the costs on health care consumers, including the costs of being denied access to critical health care information and services.

84. HHS responded to these concerns by stating only 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." *Id.* at 78,095.

85. And with respect to patients' access to vital health care services, the Department responded only, without any factual or empirical support, that "[t]his final rule does not limit patient access to health care." *Id.* at 78,093.

I. Impermissible Broadening of the Coats Amendment

86. Commenters also argued that the Proposed Regulation vastly expanded the scope of the Coats Amendment which was intended by Congress to protect only the right to refuse to participate in or provide abortion training.

87. The Department provided no response to these comments and made no change from the Proposed Regulation.

J. Limitless Individual Refusal

88. Many commenters explained that the Proposed Regulation dramatically expanded the prohibitions contained in subsection (d) of the Church Amendments beyond congressional intent to create an apparently blanket, unqualified right for employees to refuse to participate in any health services or research activities supported with HHS funds.

89. The Department provided no response to these comments and made no change from the Proposed Regulation.

K. False Claims Act Liability

90. In the Proposed Regulation, the Department specifically requested comments about whether the new certification should state that certification is a "material prerequisite" to the payment of Department funds. 73 Fed. Reg. at 50,279. Because "material prerequisite" is a term of art that often forms the basis of False Claims Act

lawsuits, commenters asked HHS about the possibility of liability under that Act, 31 U.S.C. §§ 3729-3731, as a result of certifying compliance with the Regulation.

91. The Department failed to provide an adequate response to this significant comment, which was invited by the Department itself. Without addressing the issue of liability at all, the Department answered in doublespeak 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. at 78,079.

VII. THE REGULATION'S UNAUTHORIZED EXPANSION OF THE UNDERLYING LAWS

92. None of the underlying federal laws, nor any other federal statute, delegate authority to HHS to promulgate this Regulation.

93. Even if the Department has authority to issue the Regulation, the substance of the Regulation is arbitrary, capricious, an abuse of discretion, contrary to constitutional rights and power, in excess of statutory, jurisdiction, authority, or limitations, and otherwise not in accordance for law. A non-exhaustive list of why this is so follows:

94. In light of the Department's prior statements suggesting that certain forms of contraception may be considered an abortion for purposes of the Regulation and HHS's admission that the issue is "highly controversial," its refusal to clarify how it intends to interpret the term abortion allows entities and individuals to argue that their refusals to provide contraceptive services are protected by the Regulation.

95. To the extent that the Regulation's provisions related to abortion are extended to protect refusals to provide contraceptive services and related information, the Regulation is contrary to the plain language of the underlying statutes and congressional intent.

96. To the extent that the Regulation applies to protect individuals and entities that refuse to provide patients facing medical emergencies proper medical care, it is contrary to the underlying statutes and conflicts with EMTALA.

97. By applying the restrictions contained in the Weldon Amendment to individuals and private entities, the Regulation is contrary to the clear language and intent of the Weldon Amendment which applies only to government entities.

98. By creating a right to refuse to provide information and counseling about abortion, the Regulation directly conflicts with federal laws requiring Title X projects to provide pregnant women with non-directive options counseling.

99. By extending the prohibitions contained in the Coats Amendment beyond the abortion training context, the Regulation is contrary to the clear language and intent of the Coats Amendment.

100. By applying subsection (d) of the Church Amendments to any entity "that carries out any part of any health service program or research activity" funded in whole or in part by HHS and broadly defining "individual," "workforce," and "assist in the performance of," 73 Fed. Reg. at 78,097-98, HHS has exceeded its authority.

VIII. HHS'S INADEQUATE ECONOMIC ANALYSIS AND FAILURE TO COMPLY WITH THE REGULATORY FLEXIBILITY ACT VIOLATES THE APA AND OTHER FEDERAL LAWS

101. The Regulation applies to a substantial number of small entities, as defined by the Regulatory Flexibility Act ("RFA"), including Plaintiffs.

102. The RFA requires federal agencies proposing regulations to assess the potential impact of the regulation on small entities by conducting a regulatory flexibility analysis. This analysis must consider regulatory alternatives that would minimize the impact of the regulation on small entities. However, a federal agency may be exempted from conducting this analysis if "the head of the agency certifies that the Regulation will not, if promulgated, have a significant economic impact on a substantial number of small entities." 5 U.S.C. § 605(b). The certification must be published in the notice of final rulemaking, "along with a statement providing the factual basis for such certification." *Id.*

103. In promulgating the Regulation, HHS certified that it "will not result in a significant impact on a substantial number of small entities," 73 Fed. Reg. at 78,095, without providing a sufficient factual basis for its decision.

104. Indeed, HHS failed to consider the cost to regulated entities associated with reviewing the Regulation and revising employment policies and practices; training costs associated with ensuring staff compliance; and costs related to accommodations for employees in light of the new Regulation.

105. Moreover, 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.

106. Additionally, the Congressional Review Act ("CRA"), 5 U.S.C. § 801 *et seq*., requires that federal agencies submit final regulations to Congress. Under the CRA, a "major Regulation" may not be enforced until sixty calendar days after the regulation has been both published in the Federal Register and submitted to Congress. 5 U.S.C. § 801(a)(3)(A). Major regulations are those that are determined by the Office of Information and Regulatory Affairs, in the Office of Management and Budget, to have an annual effect on the economy of $100,000,000 or more. *Id.* at § 804(2)(A).

107. Because HHS unreasonably underestimated the costs of the Regulation, it was not classified as major. A proper economic analysis would have reached the conclusion that the annual effect of the Regulation on the economy well exceeds $100 million. Thus, the Regulation should have been classified as "major," and cannot be enforced any earlier than February 17, 2009.

IX. THE REGULATION'S CATEGORICAL REQUIREMENT THAT RELIGIOUS BELIEFS BE ACCOMODATED IN THE WORKPLACE AND LACK OF CLARITY VIOLATE PLAINTIFFS' CONSTITUTIONAL RIGHTS

108. By rejecting the Title VII balancing framework and imposing on Plaintiffs an absolute, unqualified obligation to accommodate the religious objections of their employees, *see* 73 Fed. Reg. at 78,084-85, the Regulation impermissibly advances religious belief in violation of the Establishment Clause of the United States Constitution.

109. Further, as a result of the Regulation's many internal contradictions and areas of significant ambiguity, the Regulation does not provide Plaintiffs adequate

guidance as to what conduct is prohibited and encourages arbitrary enforcement in violation of the Due Process Clause of the Fifth Amendment of the United States Constitution.

X. EFFECTS OF THE REGULATION ON PLAINTIFFS' AND THEIR PATIENTS

110. The Regulation's protection for institutions and individuals who refuse to provide reproductive and other essential health care services and information will cause irreparable harm to Plaintiffs and their patients, including the estimated 17.5 million women in need of publicly funded contraceptives.

111. As a result of the Regulation, Plaintiffs will be unable to guarantee that their patients receive the full range of family planning services and information that they currently provide.

112. First, because the Regulation appears to require absolute accommodation of an employee's refusal to provide services or information related to birth control, abortion, or any other care, regardless of the burden such accommodation will impose on the health care facility's ability to serve its patients, some of Plaintiff NFPRHA's members may be forced to reduce the availability or scope of services they provide or to close entirely.

113. And, because HHS refused to require employees who intend to refuse to provide services or information to so notify their employers or their patients, neither Plaintiffs nor their patients may even be aware when a staff member is denying a patient access to needed care or information.

114. The failure to provide comprehensive, quality services, in a manner that is reasonably accessible for patients, will damage Plaintiffs' reputations as health care providers and cost them good will from patients, potential patients, and damage their ability to obtain funding from other sources.

115. Second, because the Regulation appears to forbid Title X grantees, including NFPRHA members, from "discriminat[ing]" against delegates and potential delegates that refuse to provide information about abortion and, perhaps, contraceptive services and information, grantees will be faced with a Hobson's choice: Require delegates to provide these services and risk the loss of all federal funding or allow delegates to refuse these services in violation of the requirements of Title X and many state laws, thereby also risking the loss of funding. Without such funding, many NFPRHA members will be forced to radically curtail services or to close.

116. For both of these reasons, the Regulation will seriously impede access to reproductive health care for the low-income and uninsured women who make up the vast majority of NFPRHA's members' patients. The reduction of the availability of services will have a devastating affect on Plaintiffs' patients and their families.

117. The Regulation also places Plaintiffs' patients who need emergency care for pregnancy-related complications at tremendous risk. For example, some of Plaintiffs' prenatal care patients suffer miscarriages and need emergency care that includes termination of the pregnancy. Because the Regulation contains no explicit exception for emergencies, Plaintiffs' patients are in danger of being denied treatment in the hospital. Such denials put Plaintiffs' patients at risk for serious harm to their health, including hemorrhage, sepsis, infertility, and even death. The Regulation places Plaintiffs' patients

who seek emergency treatment for ectopic pregnancies or abortion complications at similar risk.

118. The Regulation puts Plaintiffs' patients who are survivors of sexual assault at particular risk of harm. Both accepted medical standards and the laws of many states require hospitals that treat rape survivors to offer them emergency contraception. Because the Regulation leaves the door open for individuals and institutions to erroneously define hormonal contraceptives such as EC as "abortions," however, some individuals and institutions will use the Regulation to deny EC to such patients resulting in additional psychological trauma and unwanted pregnancies.

119. In addition, in light of HHS's statements that the Regulation offers protections for employees "that are distinct from, and extend beyond Title VII," and that the choice is no longer "between reasonable accommodations and undue burden, but between accommodation . . . and federal funding," 73 Fed. Reg. at 78,085, the Regulation forces Plaintiffs' members to expend considerable resources to modify their employment policies and to re-train their employees. Some members who are also Title X grantees will also need to expend additional resources to help their sub-grantees come into compliance with the Regulation.

120. All told, the Regulation places Plaintiffs at risk of losing hundreds of millions of dollars of federal funds if they continue to attempt to provide their patients with the comprehensive reproductive health services and high standard of care to which they are committed. Many of Plaintiff NFPRHA's members would have to discontinue providing these essential services altogether if they lost their HHS funding.

121. Failure to comply with this vague and confusing Regulation also puts Plaintiffs at risk of "whistleblower" lawsuits under the False Claims Act, 31 U.S.C. §§ 3729-3731, which permits the federal government and private parties to seek civil penalties for the submission of false claims.

XI. CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF

122. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein.

123. The Regulation is, *inter alia*, arbitrary, capricious, an abuse of discretion, and promulgated 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.

SECOND CLAIM FOR RELIEF

124. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein.

125. The Regulation, and its mandatory certification requirement, violate the Administrative Procedure Act, 5 U.S.C. § 706(2), because the underlying laws do not delegate authority to HHS to promulgate regulations with the force of law.

THIRD CLAIM FOR RELIEF

126. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein.

127. The Regulation is, *inter alia*, arbitrary, capricious, an abuse of discretion, not in accordance with law, in excess of statutory jurisdiction, authority, or limitations, or short of statutory right, in violation of the Administrative Procedure Act, 5 U.S.C. § 706(2), because, among other things:

a. the term "abortion" in the underlying statutes does not include contraception;

b. the underlying statutes do not apply in emergencies or preempt laws requiring the provision of emergency care;

c. it contravenes the requirement that all pregnancy counseling provided in the Title X program be non-directive and offer women the opportunity to be informed about abortion;

d. it expands the Weldon Amendment to reach individuals and private entities;

e. it extends the application of the Coats Amendment beyond the abortion training context;

f. it extends the application of subsection (d) of the Church Amendment beyond the biomedical and behavioral research context;

g. it impermissibly expands the meaning of other terms such as "assist in the performance."

FOURTH CLAIM FOR RELIEF

128. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein.

129. In promulgating the Regulation, HHS acted in violation of the Administrative Procedure 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 regulation.

FIFTH CLAIM FOR RELIEF

130. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein.

131. To the extent that the Regulation imposes on Plaintiffs a categorical requirement to accommodate employees' religious objections to providing health care services – regardless of the impact on the employer's business, other employees, or patients – the Regulation violates the Establishment Clause of the First Amendment of the United States Constitution.

SIXTH CLAIM FOR RELIEF

132. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein.

133. By failing to provide adequate guidance about what conduct is prohibited and by encouraging arbitrary enforcement, the Regulation violates Plaintiffs' rights to due process guaranteed by the Fifth Amendment of the United States Constitution.

SEVENTH CLAIM FOR RELIEF

134. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein.

135. By interfering with women's ability to obtain abortions necessary to preserve their health or life, the Regulation violates Plaintiffs' patients' rights to privacy and liberty guaranteed by the Fifth Amendment of the United States Constitution.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray that the Court:

1. Issue injunctive relief prohibiting implementation or enforcement of the Regulation;

2. Enter a declaratory judgment that the Regulation is invalid;

3. Award such further and additional relief as is just and proper, including reasonable attorneys' fees and costs.

Dated:

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*Admission *pro hac vice* pending