Case No. 12-2673

IN THE UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

AUTOCAM CORPORATION; AUTOCAM MEDICAL, LLC; JOHN KENNEDY; PAUL KENNEDY; JOHN KENNEDY, IV; MARGARET KENNEDY; THOMAS KENNEDY,

Plaintiffs-Appellants,

v.

KATHLEEN SEBELIUS, in her official capacity as Secretary of the United States Department of Health and Human Services, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; SETH D. HARRIS, in his official capacity as Acting Secretary of Labor; UNITED STATES DEPARTMENT OF LABOR; JACOB LEW, in his official capacity as Secretary of the Treasury; UNITED STATES DEPARTMENT OF THE TREASURY,

Defendants-Appellees.

On Appeal from the United States District Court
Western District of Michigan
The Honorable Robert J. Jonker
Case No. 1:12-CV-1096

Brief of National Health Law Program, Mexican American Legal Defense and Educational Fund, Asian Pacific American Legal Center, Black Women's Health Imperative, Forward Together, National Hispanic Medical Association, Ipas, Sexuality Information and Education Council of the U.S. (SIECUS), Campaign to End AIDS, HIV Law Project, National Women and AIDS Collective, and Housing Works as *Amicus Curiae*

Supporting Defendants-Appellees and Supporting Affirmance
Filed with Consent of All Parties

National Health Law Program
Martha Jane Perkins
101 East Weaver Street, Suite G-7
Carrboro, North Carolina 27510
Tel.: (919) 968-6308

UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

Disclosure of Corporate Affiliations and Financial Interest

Sixth Circuit
Case Number: 12-2673 Case Name: Autocam Corp. v. Kathleen Sebelius

Name of counsel: Martha J. Perkins

Pursuant to 6th Cir. R. 26.1, Amici, National Health Law Program, et al.
Name of Party

makes the following disclosure:

1. Is said party a subsidiary or affiliate of a publicly owned corporation? If Yes, list below the identity of the parent corporation or affiliate and the relationship between it and the named party:

No.

2. Is there a publicly owned corporation, not a party to the appeal, that has a financial interest in the outcome? If yes, list the identity of such corporation and the nature of the financial interest:

No.

CERTIFICATE OF SERVICE

I certify that on March 21, 2013 the foregoing document was served on all parties or their counsel of record through the CM/ECF system if they are registered users or, if they are not, by placing a true and correct copy in the United States mail, postage prepaid, to their address of record.

s/Martha J. Perkins
101 East Weaver Street, Suite G-7
Carrboro, North Carolina 27510

This statement is filed twice: when the appeal is initially opened and later, in the principal briefs, immediately preceding the table of contents. See 6th Cir. R. 26.1 on page 2 of this form.

6th Cir. R. 26.1
DISCLOSURE OF CORPORATE AFFILIATIONS AND FINANCIAL INTEREST

(a) **Parties Required to Make Disclosure.** With the exception of the United States government or agencies thereof or a state government or agencies or political subdivisions thereof, all parties and amici curiae to a civil or bankruptcy case, agency review proceeding, or original proceedings, and all corporate defendants in a criminal case shall file a corporate affiliate/financial interest disclosure statement. A negative report is required except in the case of individual criminal defendants.

(b) **Financial Interest to Be Disclosed.**

(1) Whenever a corporation that is a party to an appeal, or which appears as amicus curiae, is a subsidiary or affiliate of any publicly owned corporation not named in the appeal, counsel for the corporation that is a party or amicus shall advise the clerk in the manner provided by subdivision (c) of this rule of the identity of the parent corporation or affiliate and the relationship between it and the corporation that is a party or amicus to the appeal. A corporation shall be considered an affiliate of a publicly owned corporation for purposes of this rule if it controls, is controlled by, or is under common control with a publicly owned corporation.

(2) Whenever, by reason of insurance, a franchise agreement, or indemnity agreement, a publicly owned corporation or its affiliate, not a party to the appeal, nor an amicus, has a substantial financial interest in the outcome of litigation, counsel for the party or amicus whose interest is aligned with that of the publicly owned corporation or its affiliate shall advise the clerk in the manner provided by subdivision (c) of this rule of the identity of the publicly owned corporation and the nature of its or its affiliate's substantial financial interest in the outcome of the litigation.

(c) Form and Time of Disclosure. The disclosure statement shall be made on a form provided by the clerk and filed with the brief of a party or amicus or upon filing a motion, response, petition, or answer in this Court, whichever first occurs.

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STATEMENT OF INTEREST[1]

The *amici* are National Health Law Program, Mexican American Legal Defense and Educational Fund, Asian Pacific American Legal Center, Black Women's Health Imperative, Forward Together, National Hispanic Medical Association, Ipas, Sexuality Information and Education Council of the U.S. (SIECUS), Campaign to End AIDS, HIV Law Project, National Women and AIDS Collective, and Housing Works. While each *Amicus* has particular interests, they share the mission of ensuring that all people in the United States—including women—have access to affordable, quality health care, including preventive health services. The *amici* submit this brief pursuant to Fed. R. App. P. 29 to highlight well-established standards of medical care and prevailing federal laws and policies pre-dating the Patient Protection and Affordable Care Act (ACA) that recognize that family planning services are essential preventive care for women.

ARGUMENT

I. Accepted evidence-based standards of medical care recognize that contraception is essential preventive care for women.

This case concerns the ACA and U.S. Department of Health and Human Services' (HHS) requirement that most new health insurance plans cover women's preventive health services, including contraception.[2] This requirement is in

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[1] The parties consented to the filing of this brief. No party's counsel authored this brief in whole or in part. No party or party's counsel contributed money to fund preparation or submission of this brief. No person, other than *amici* and *amici*'s counsel, contributed money to fund preparation or submission of this brief.

[2] *See* Patient Protection & Affordable Care Act (ACA), Pub. L. No. 111-148, § 1001, § 2713(a), 124 Stat. 131 (2010) (codified at 42 U.S.C. § 300gg-13); 45 C.F.R. § 147.130(b)(1); U.S. Dep't of Health & Human Servs. (HHS), Health Res.

accord with accepted standards of medical care recognized by the various professional medical academies.

According to the American Medical Association's (AMA) Council on Ethical and Judicial Affairs, a standard of care is "'that level of care, skill and treatment' . . . which a 'reasonable and prudent [physician] similarly situated would provide under similar circumstances.'"[3] The standards are based on "information from experience that has met some established set of validity, and the appropriate standard is determined according to the requirements of the intervention and clinical circumstance."[4] Researchers consider a variety of evidence in developing standards. Generally, standards are based on large quantities of evidence from empirical studies, but clinicians' practice experiences may also contribute to the development of standards.[5]

Prevailing standards of medical care recognize family planning services as a necessary component of preventive care for women. These standards are reflected in the formal practice recommendations of health care professional associations such as the American Congress of Obstetricians and Gynecologists (ACOG), the Society for Family Planning, the American Academy of Pediatrics (AAP), the Society for Adolescent Medicine, the AMA, the American Public Health

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& Servs. Admin., *Women's Preventive Services: Required Health Plan Coverage Guidelines*, http://www.hrsa.gov/womensguidelines.

[3] Am. Med. Ass'n (AMA) Council on Ethical & Judicial Affairs, Council on Ethical & Judicial Affairs Rep. 12-A-04, at 3 (2004) (footnote omitted) (citations omitted) (defining standard of care in context of medical testimony in legal proceedings).

[4] Inst. of Med. of the Nat'l Acads. (IOM), *Roundtable on Value & Science-Driven Health Care* 3 (July 2011) (defining evidence).

[5] Nat'l Health Law Program, *Health Care Refusals: Undermining Quality Care for Women* 8 (2010) (defining standard of care).

Association (APHA), and the Association of Women's Health, Obstetric and Neonatal Nurses, all of which "recommend use of family planning as part of preventive care for women."[6] For example, ACOG recommends that women have access to family planning services.[7] According to the American Academy of Family Physicians, effective contraceptive use is a component of preconception care for all women who are not planning to become pregnant.[8] The APHA has endorsed universal access to contraception for over thirty years.[9]

Similarly, the U.S. Centers for Disease Control and Prevention's (CDC) Agency for Toxic Substances and Disease Registry concludes that preconception (before pregnancy) and inter-conception (between pregnancies) care should include family planning counseling along with increased health insurance coverage of contraceptives because, among other things, this coverage can reduce the risk of maternal and infant mortality and pregnancy-related complications.[10] The AMA

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[6] *See* IOM, *Clinical Preventive Services for Women: Closing the Gaps* 104 (2011) [hereinafter IOM, *Closing the Gaps*] (citing Kay Johnson et al., *Recommendations to Improve Preconception Health and Health Care—United States: A Report of the CDC/ATSDR Preconception Care Work Group and the Select Panel on Preconception Care*, 55 MORBIDITY & MORTALITY WKLY. REP. 1 (2006) (discussing practice guidelines)).

[7] *See, e.g.*, Am. Cong. of Obstetricians & Gynecologists (ACOG), Technical Bulletin No. 205, *Preconception Care* (1995); ACOG Comm. on Gynecologic Practice, Comm. Op. No. 313, *The Importance of Preconception Care in the Continuum of Women's Health Care*, 106 OBSTETRICS & GYNECOLOGY 656, 656-66 (2005).

[8] Michael C. Lu et al., *Recommendations for Preconception Care*, 76 AM. FAMILY PHYSICIAN 397, 399-400 (2007).

[9] Am. Pub. Health Ass'n, *Population: Family Planning as an Integral Part of Health Services*, Pol. No. 7518 (Jan. 1, 1975), *available at* http://www.apha.org/advocacy/policy/policysearch/default.htm?id=1335.

[10] Kay Johnson et al., *supra* note 6, at 14, 17, 19-20.

supports these CDC recommendations.[11]

AAP and ACOG further recommend that every visit with a woman's clinician include a reproductive health screen and counseling.[12] If pregnancy is not desired, AAP and ACOG standards call for the clinician and patient to discuss contraceptive options and proper use of the woman's chosen contraceptive method.[13] The discussion with the woman's provider is to "assist the [woman] in identifying the most appropriate and effective method for her" needs.[14]

A. Standards of care recommend effective contraceptive use for pregnancy spacing.

Unintended pregnancy is associated with poor health outcomes, maternal morbidity and mortality, and risky health behaviors. The World Health Organization's standards of care recommend that a woman space her pregnancy at least two years apart so that the body can properly recover.[15] According to ACOG, women who become pregnant less than six months after their previous pregnancy are seventy percent more likely to have membranes surrounding the fetus rupture prematurely and are at significantly higher risk of other complications.[16] Research also shows that short birth intervals are associated with higher than average low

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[11] AMA House of Delegates, Policy No. H-425.976 (adopted 2009).

[12] Am. Acad. of Pediatrics & ACOG, *Guidelines for Perinatal Care* 101 (7th ed. 2012); *see also* ACOG Comm. on Gynecologic Practice, *supra* note 7 (referring to guidelines for perinatal care and women's health care).

[13] *See* Am. Acad. of Pediatrics & ACOG, *supra* note 12, at 101.

[14] *Id.*

[15] Cicley Marston, *Report of a WHO Technical Consultation on Birth Spacing* 2 (June 13-15, 2005).

[16] Thomas Gellhaus, Statement of ACOG to the U.S. Senate, Comm. on Health, Educ., Labor & Pensions, Pub. Health Subcomm.: Safe Motherhood (Apr. 25, 2002).

birth weights and neonatal death.[17] Thus, the professional academies, including the AMA and ACOG, recommend that women have access to contraceptive counseling and services, which will enable them to appropriately space their pregnancies.[18]

B. Standards of care recommend that women taking drugs contraindicated for pregnancy have access to contraception.

Access to contraception is critical for pregnant women taking medications that pose serious risks for maternal and fetal health. A number of commonly prescribed pharmaceuticals are known to cause impairments in the developing fetus or to create adverse health conditions for the pregnant woman.[19]

Approximately 11.7 million prescriptions for drugs the U.S. Food & Drug Administration (FDA) has categorized as Pregnancy Category D (there is evidence of fetal harm, but potential benefits may warrant use despite the harm) or Category X (contraindicated in women who are or may become pregnant because the risks of use of the drugs by a pregnant woman outweigh the potential benefits) are filled by significant numbers of women of reproductive age each year.[20] Approximately

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[17] *See, e.g.*, James S. Rawlings, *Prevalence of Low Birth Weight and Preterm Delivery in Relation to the Interval between Pregnancies among White and Black Women*, 322 N. ENG. J. MED. 69, 69 (1995) (citing studies).

[18] *See* discussion *supra* at pp. 1-4.

[19] David L. Eisenberg et al., *Providing Contraception for Women Taking Potentially Teratogenic Medications: A Survey of Internal Medicine Physicians' Knowledge, Attitudes and Barriers*, 25 J. GEN. INTERNAL MED. 291, 291-92 (2010); Susan E. Andrade et al., *Prescription Drug Use in Pregnancy*, 191 AM. J. OBSTETRICS & GYNECOLOGY 398, 406 (2004).

[20] Eleanor B. Schwarz et al., *Documentation of Contraception and Pregnancy When Prescribing Potentially Teratogenic Medications for Reproductive-Age Women*, 147 ANNALS OF INTERNAL MED. 370, 370 (2007) [hereinafter Schwarz et al., *Documentation of Contraception*]; Eleanor B. Schwarz et al., *Prescription of Teratogenic Medications in United States Ambulatory Practices*, 118 AM. J. MED. 1240, 1240-41 (2005).

5.8% of pregnancies in the United States are exposed to Category D or X drugs.[21] Multiple studies recommend that women at risk for pregnancy and taking these drugs use a reliable form of contraception to prevent pregnancy.[22]

For example, Isotretinoin, a drug to treat severe cystic acne, can cause multiple fetal impairments.[23] The FDA recommends that women of reproductive age who are taking this drug agree to use two forms of contraception.[24] Iodine 131 is another example of a drug for which pregnancy is contraindicated because it may destroy the developing fetus.[25] Iodine 131 is used to treat hyperthyroidism and thyroid cancer. ACOG recommends that women taking Iodine 131 avoid pregnancy.[26]

C. Standards of care recommend that women with heart conditions have access to contraception.

Heart disease is the number one cause of death for women in the United States.[27] African American women have twice the age standardized rate of fatal

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[21] David L. Eisenberg et al., *supra* note 19, at 291.

[22] *See, e.g.*, *id.* at 291-92; Schwarz et al., *Documentation of Contraception*, *supra* note 20, at 374-75.

[23] Ctrs. for Disease Control & Prevention (CDC), *Accutane®—Exposed Pregnancies*, 21 MORBIDITY & MORTALITY WKLY. REPT. 28, 28 (2000).

[24] U.S. Food & Drug Admin., *iPledge Program Frequently Asked Questions As of July 21, 2006*, at 5 (2006), http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm094313.pdf.

[25] ACOG Comm. on Practice Bulletins, Practice Bulletin No. 37: Clinical Management Guidelines for Obstetrician—Gynecologists, *Thyroid Disease in Pregnancy* 5 (2002).

[26] *Id.*

[27] CDC, *Women and Heart Disease Fact Sheet* (last visited March 7, 2013), http://www.cdc.gov/dhdsp/data_statistics/fact_sheets/docs/fs_women_heart.pdf.

incidence of cardiovascular disease as white women.[28] There are a number of cardiac conditions in which the physiological changes brought about in pregnancy are poorly tolerated, including valvular heart lesions.[29]

For example, the American College of Cardiology and the American Heart Association Task Force on Practice Guidelines have issued specific recommendations for management of women with valvular heart disease.[30] These guidelines recommend that preconception management include provision of information about contraception and maternal and fetal risks of pregnancy.[31] These professional associations recommend that clinicians counsel women with certain heart conditions, including valvular heart disease, against pregnancy.[32] The decision of whether to use contraception is, however, ultimately left to the woman.[33]

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[28] Monika M. Safford et al., *Association of Race and Stroke with Risk of Incident Acute Coronary Heart Disease Events*, 308 J. AM. MED. ASS'N 1768, 1772 (2012).

[29] Robert O. Bonow et al., *2008 Focused Update Incorporated Into the ACC/AHA 2006 Guidelines for the Management of Patients With Valvular Heart Disease*, 118 CIRCULATION e523, e598-e604 (2008).

[30] Robert O. Bonow et al., *Guidelines for the Management of Patients with Valvular Heart Disease: Executive Summary Report of the of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee on Management of Patients With Valvular Heart Disease)* 98 CIRCULATION 1949 (1998).

[31] *Id.* at 1974.

[32] Bonow et al., *2008 Focused Update Incorporated Into the ACC/AHA 2006 Guidelines for the Management of Patients With Valvular Heart Disease*, *supra* note 29, at e598-99.

[33] *See, e.g.*, Am. Acad. of Pediatrics & ACOG, *supra* note 12, at 101 ("If pregnancy is not desired, current contraceptive use and options should be discussed to assist the patient in identifying the most appropriate and effective method for her.").

D. Standards of care recommend that women with diabetes have access to contraception.

Standards of medical care also advise women with diabetes to prevent pregnancy until their condition is under control. People with diabetes either produce insufficient insulin or cannot properly use insulin.[34] Pregestational diabetes mellitus is a type of diabetes in women that develops before they become pregnant.[35] An estimated ten to eighteen percent of nonpregnant women of reproductive age have some type of abnormal glucose tolerance that carries maternal and fetal risks if they became pregnant.[36] Pregestational diabetes occurs in approximately one percent of all pregnancies.[37] The diabetes prevalence rate is higher for women of color.[38]

The failure to manage glucose levels during pregnancy can lead to serious complications and harm maternal and infant health.[39] For example, women with poorly controlled pregestational diabetes are at an increased risk of hypoglycemia, blindness, complications from chronic hypertension, and life-threatening

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[34] CDC, *National Diabetes Fact Sheet, 2007* (2007), http://www.cdc.gov/diabetes/pubs/pdf/ndfs_2007.pdf.

[35] *Id.*

[36] Thomas Buchanan, DIABETES IN AM. 720 (Nat'l Diabetes Data Group et al. eds., 2d ed. 1995).

[37] ACOG Comm. on Practice Bulletins, Practice Bulletin No. 60, *Pregestational Diabetes Mellitus* [hereinafter ACOG Comm. on Practice Bulletins, Practice Bulletin No. 60], 105 OBSTETRICS & GYNECOLOGY 675, 675 (2005).

[38] HHS, Nat'l Diabetes Info. Clearinghouse, *Diabetes Overview*, http://diabetes.niddk.nih.gov/dm/pubs/overview/#scope; Ann S. Barnes, *The Epidemic of Obesity and Diabetes: Trends and Treatments*, 38 TEX. HEART INST. J. 142, 142 (2011).

[39] ACOG Comm. on Practice Bulletins, Practice Bulletin No. 60, *supra* note 37, at 676-77.

complications from coronary heart disease.[40] Further, diabetic nephropathy, a significant complication of diabetes, the leading cause of renal failure, and a critical factor affecting pregnancy outcomes, affects six percent of pregnant women with type I diabetes.[41] The failure to manage glucose preconception has been linked to congenital fetal impairment and spontaneous abortion.[42]

The American Diabetes Association (ADA) and ACOG have issued standards of practice guidelines for the preconception care for women with pregestational diabetes. According to the ADA, "planned pregnancies greatly facilitate diabetes care."[43] The ADA standards of care for women with diabetes with childbearing potential includes: (1) "use of effective contraception at all times, unless the patient has good metabolic control and is actively trying to conceive" and (2) counseling about the risk of fetal impairment associated with unplanned pregnancies and poor metabolic control.[44] ACOG recommends that women have glucose levels under control before becoming pregnant to decrease the likelihood of spontaneous abortion, fetal malformation, and fetal or infant death.[45]

E. Standards of care recommend that women with lupus have access to contraception.

Contraception is a critical service for women with lupus. Lupus is an auto-

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[40] *Id.* at 677-78.

[41] E. Albert Reece et al., *Pregnancy in Women with Diabetic Neuropathy*, in UpToDate (2012).

[42] Am. Diabetes Ass'n (ADA), *Preconception Care of Women with Diabetes*, 27 DIABETES CARE S76, S76 (2004).

[43] ADA, *Standards of medical care in diabetes-2006*, 29 DIABETES CARE S13, S43 (2006).

[44] *Id.*

[45] ACOG Comm. on Practice Bulletins, Practice Bulletin No. 60, *supra* note 37, at 681.

immune disorder with multiple end-organ involvement that can affect multiple parts of the body, including skin, joints, blood, and kidneys.[46] Often called a "woman's disease," nine out of ten people with lupus are women.[47] The incidence rate for lupus is three times higher for African American women than for Caucasian women.[48] Women with lupus who become pregnant face particularly increased risks of health complications.[49] A large review of U.S. hospital data found that the risk of maternal death for women with lupus is twenty times the risk for non-lupus pregnant women.[50] Women with lupus are three to eight times more likely to suffer from thrombosis, infection, renal failure, hypertension, and preeclampsia.[51]

The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) has issued a standard of care recommending that women and physicians take these health risks and complications into consideration in determining whether to become pregnant or to carry a pregnancy to term and that providers counsel women to use contraception until their condition is under control.[52] Because of the multiple and life-threatening risks associated with lupus, NIAMS recommends that

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[46] HHS, Office on Women's Health, *Lupus: Frequently Asked Questions* 1-2 (June 13, 2001), http://www.womenshealth.gov/publications/our-publications/fact-sheet/lupus.pdf.

[47] *Id.* at 2.

[48] *Id.*

[49] *Id.* at 11; *see, e.g.*, Megan E.B. Clowse et al., *A national study of the complications of lupus in pregnancy*, 199 AM. J. OBSTET. & GYNECOL. 127e.1, 127e.3 (Aug. 2008).

[50] *Id.*

[51] *Id.* at 127e.1, e.3-e.4.

[52] Nat'l Inst. of Arthritis & Musculoskeletal & Skin Diseases, *Lupus: A Patient Care Guide for Nurses and Other Health Professionals* 45-47, Patient Info. Sheet 4-5 (3d ed. 2006).

women delay pregnancy until there are no signs or symptoms of lupus.[53] The NIAMS standard accordingly instructs women with lupus to use contraception: "Do not stop using your method of birth control until you have discussed the possibility of pregnancy with your doctor and he or she has determined that you are healthy enough to become pregnant."[54] The CDC's clinical guidance similarly concludes that unintended pregnancy presents an unacceptable health risk for women with lupus and, therefore, recommends that clinicians advise women with lupus that using only barrier or behavior-based methods of contraception may not be appropriate.[55]

Practice guidelines are clear: women require information about and access to contraceptives to prevent pregnancy. By requiring new group health plans and health insurance issuers to cover women's preventive care services, the ACA recognizes that women have unique reproductive and gender-specific health needs.[56] HHS' decision to adopt the IOM's recommendation that women receive coverage for all FDA-approved methods of contraception free of cost-sharing is good medical policy that comports with well-established standards of medical care.[57]

II. Contraception is widely available through federal laws and policies pre-dating the ACA.

The ACA and HHS coverage provisions reflect a long history of federal

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[53] *Id.* at Patient Info. Sheet No. 11.

[54] *Id.* at Patient Info. Sheet No. 4.

[55] CDC, *U.S. Medical Eligibility Criteria for Contraceptive Use*, 59 MORBIDITY & MORTALITY WKLY. REP. 4, 6 (2010).

[56] ACA § 1001, § 2713(a)(4), 42 U.S.C. § 300gg-13.

[57] *See* 45 C.F.R. § 147.130(b)(1); HHS, Health Res. & Servs. Admin., *Women's Preventive Services: Required Health Plan Coverage Guidelines*, *supra* note 2.

legislation through which preventive contraceptive counseling, services, and supplies are widely available. In 1973, for example, Congress enacted the Health Maintenance Organization (HMO) Act to encourage the delivery of health care through the HMO model.[58] The Act applies to private health plans that apply for federal qualification, a designation that enables HMOs to, among other things, avoid state laws more restrictive than the HMO Act.[59] The HMO Act identifies basic health services that qualified HMOs must provide enrollees, as well as supplemental services that they can choose to provide.[60] "Basic health services" include "family planning services."[61]

The Federal Employees Health Benefits (FEHB) program also covers family planning services. The FEHB program provides employee health benefits to civilian government employees and annuitants of the U.S. government.[62] The U.S. Office of Personnel Management contracts with qualified private insurance carriers to offer health care plans through the FEHB program.[63] As part of the Omnibus

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[58] Pub .L. No. 93-222, § 1, 87 Stat. 914 (1973) (codified at 42 U.S.C. §§ 300e-300e-17); *see also* S. Rep. No. 93-129, at 3037-41 (1973) (stating purpose of Act to "provide assistance and encouragement for the establishment and expansion of health maintenance organizations").

[59] 42 U.S.C. §§ 300e (defining HMO as a "public or private entity"), 300e-5 (application requirements), 300e-10 (stating that restrictive state laws do not apply to federally qualified HMOs).

[60] *Id.* § 300e-1.

[61] *Id.* §§ 300e-1(1)(H)(iv) (defining "basic health service"), 300e (requiring HMO to cover "basic and supplemental health services").

[62] *See* 5 U.S.C. §§ 8901-14 (health insurance for government employees), 8905(a)-(b) (defining eligible persons).

[63] *Id.*; *Muratore v. U.S. Office of Pers. Mgmt.*, 222 F.3d 918, 920 (11th Cir. 2000) ("Congress enacted the FEHBA . . . to create a comprehensive program of subsidized health care benefits for federal employees and retirees."); U.S. Office of Pers. Mgmt., *The Fact Book, Federal Civilian Workforce Statistics* 82 (2007), http://www.opm.gov/feddata/factbook/.

Consolidated and Emergency Supplemental Appropriations Act of 1999, Congress approved a "contraceptive equity provision" requiring most FEHB plans to cover contraception.[64] Accordingly, the U.S. Office of Personnel Management, which administers the FEHB program, requires all FEHB plans to cover the full range of FDA-approved contraceptive drugs and devices.[65] As amended in 1998, the FEHB program includes specifically enumerated religious health plans that did not cover contraception, and authorizes inclusion of future plans objecting to such coverage "on the basis of religious beliefs."[66] However, the decision of whether to take up contraceptive coverage is left to the employee, who can choose from up to 300 plans.[67] This is qualitatively different from the position advanced by Appellants, namely a refusal clause that would allow any employer to opt out of providing female employees preventive health care benefits because of the employer's religious beliefs. Unlike the FEHB program, the Appellants' proposal leaves employees without preventive care coverage.

Federal legislation regulating the health services available to military personnel and their families also requires coverage of preventive contraceptive services. Congress established a military health system to "create and maintain high morale in the uniformed services by providing an improved and uniform program of medical and dental care for members and certain former members of

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[64] Omnibus Consolidated & Emergency Supplemental Appropriations Act of 1999, Pub. L. No. 105-277, § 656(a), 112 Stat. 2681 (1998).

[65] U.S. Office of Pers. Mgmt., Benefits Admin. Ltr. No. 98-418 (Nov. 6, 1998).

[66] Omnibus Consolidated & Emergency Supplemental Appropriations Act of 1999, Pub. L. No. 105-277, § 656(b), 112 Stat. 2681 (1998).

[67] U.S. Office of Pers. Mgmt., *Federal Employees Health Benefits Program Patients' Bill of Rights and the Federal Employees Health Benefits Program* (last visited March 7, 2013), http://www.opm.gov/insure/archive/health/billrights.asp#Choice.

those services, and for their dependents."[68] Pursuant to congressionally delegated authority, the Department of Defense established the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS) in 1967 (now known as TRICARE).[69] In 1995, the Department of Defense established TRICARE as a "comprehensive managed health care program for the delivery and financing of health care services in the Military Health System."[70] TRICARE provides health care benefits to active-duty service members, retirees and their families, and other beneficiaries from any of the seven services.[71] TRICARE offers all beneficiaries a range of FDA-approved methods of contraception, including intrauterine devices, diaphragms, prescription contraceptives, and surgical sterilization.[72]

Congress' declaration of a national policy of "ensur[ing] the highest possible health status for Indians and urban Indians" also includes the requirement that health plans cover family planning services and supplies.[73] Among other things, Congress authorized the Secretary of HHS, acting through the Indian Health Service (IHS), "to provide health promotion and disease prevention services to Indians . . . ."[74] Congress's definition of "health promotion" includes programs for "reproductive health and family planning."[75] According to the IHS manual, IHS

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[68] 10 U.S.C. § 1071.

[69] Pub. L. No. 85-861, § 1(25)(B), 72 Stat. 1445 (1958), amended by Pub. L. No. 89-614, § 2(1), 80 Stat. 862 (1966).

[70] 32 C.F.R. §§ 199.17(a), 199.3; 10 U.S.C. § 1073(2).

[71] *See* 10 U.S.C. §§ 1072 (defining TRICARE), 1074 (providing for medical and dental care for members and certain former members of armed forces), 1077 (providing for medical and dental care for dependents).

[72] 32 C.F.R. § 199.4(e)(3); 10 U.S.C. § 1077 (preventive health care services for women includes pregnancy prevention).

[73] 25 U.S.C. § 1602(1)-(2).

[74] *Id.* § 1621b(a).

[75] *Id.* § 1603(11)(G)(xix).

"provide[s] comprehensive family planning services to all eligible American Indian and Alaska Native men and women."[76] This includes, "[a]ll available Food and Drug Administration (FDA) approved types of contraceptive (mechanical, chemical and natural) methods," with the woman deciding the appropriate choice of method.[77]

Coverage of family planning services and supplies is also a requirement of Medicaid—the country's largest public health insurance program covering approximately 60 million low-income people.[78] States participating in Medicaid receive significant federal funding in return for providing specified health insurance coverage to specified groups of people (with a state option to cover additional groups and services). The Medicaid Act requires participating states to cover family planning services and supplies for all categorically needy beneficiaries.[79]

The ACA's contraceptive coverage provision is not unique. Standards of medical care recognize that a woman's ability to use contraception is critical to her health and well-being. The federal government has long-recognized these standards of medical care by enacting laws and policies that ensure women's access to health insurance benefits that include contraception coverage.

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[76] HHS, Indian Health Serv., Indian Health Serv. Manual § 3-13.12B(1).

[77] *Id.* §§ 3-13.12F(2), 3-13.12B(1).

[78] *See* 42 U.S.C. § 1396-1396w-5; *see Wilder v. Va. Hosp. Ass'n*, 496 U.S. 498, 502 (1990) ("Although participation in the program is voluntary, participating states must comply with certain requirements imposed by the Act and regulations.

[79] 42 U.S.C. § 1396d(a)(4)(c); 42 C.F.R. § 441.20; *See* Ctrs. for Medicare & Medicaid Srvs., State Medicaid Manual § 4270; Ctrs. for Medicare & Medicaid Srvs., *Dear State Medicaid Director* (July 2, 2010) (discussing family planning related services in context of new eligibility option under ACA § 2303).

CONCLUSION

The *amici* urge this Court to affirm the decision of the District Court.

March 21, 2013

Respectfully submitted,

/s/Martha Jane Perkins
Martha Jane Perkins
National Health Law Program
101 East Weaver Street, Suite G-7
Carrboro, North Carolina 27510
Tel.: (919) 968-6308

CERTIFICATE OF COMPLIANCE

I hereby certify that this brief complies with the requirements of Fed. R. App. P. 32(a)(5) and (6) because it has been prepared in 14-point Times New Roman, a proportionally spaced font. I certify that the foregoing brief complies with the requirements of Fed. R. App. P. 29(d) and that the total number of words in this brief, exclusive of the Table of Contents, Table of Authorities, and this Certificate is 4153 words, according to the count of Microsoft Word.

/s/ Martha Jane Perkins
Martha Jane Perkins

CERTIFICATE OF SERVICE

I hereby certify that on March 21, 2013, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the Eighth Circuit by using the appellate CM/ECF system. The participants in the case are registered CM/ECF users, and service will be accomplished by the appellate CM/ECF system.

/s/ Martha Jane Perkins
Martha Jane Perkins