

**[ORAL ARGUMENT REQUESTED]**

Case No. 14-6028

**IN THE UNITED STATES COURT OF APPEALS  
FOR THE TENTH CIRCUIT**

REACHING SOULS INTERNATIONAL, INC., an Oklahoma non-profit corporation, et  
al.

*Plaintiffs-Appellees,*

v.

KATHLEEN SEBELIUS, Secretary of the U.S. Department of Health and Human Services, et  
al.,

*Defendants-Appellants.*

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*On Appeal from the United States District Court for the Western District of Oklahoma  
(No. 13-cv-1092 (DeGiusti, J.))*

**BRIEF OF NATIONAL HEALTH LAW PROGRAM, AMERICAN PUBLIC HEALTH  
ASSOCIATION, NATIONAL FAMILY PLANNING & REPRODUCTIVE HEALTH  
ASSOCIATION, NATIONAL WOMEN'S HEALTH NETWORK, NATIONAL LATINA  
INSTITUTE FOR REPRODUCTIVE HEALTH, NATIONAL ASIAN PACIFIC  
AMERICAN WOMEN'S FORUM, ASIAN AMERICANS ADVANCING JUSTICE |  
AAJC, ASIAN AMERICANS ADVANCING JUSTICE | LOS ANGELES, ASIAN &  
PACIFIC ISLANDER AMERICAN HEALTH FORUM, BLACK WOMEN'S HEALTH  
IMPERATIVE, FORWARD TOGETHER, IPAS, SEXUALITY INFORMATION AND  
EDUCATION COUNCIL OF THE U.S. (SIECUS), HIV LAW PROJECT, NATIONAL  
WOMEN AND AIDS COLLECTIVE, AND CALIFORNIA WOMEN'S LAW CENTER  
AS *AMICI CURIAE* IN SUPPORT OF DEFENDANTS-APPELLANTS**

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## CORPORATE DISCLOSURE STATEMENT

Pursuant to Fed. R. App. P. 26.1 and Circuit Rule 26.1(a), the undersigned counsel certifies that the *amici curiae* National Health Law Program, American Public Health Association, National Family Planning & Reproductive Health Association, National Women's Health Network, National Latina Institute for Reproductive Health, National Asian Pacific American Women's Forum, Asian Americans Advancing Justice | AAJC, Asian Americans Advancing Justice | Los Angeles, Asian & Pacific Islander American Health Forum, Black Women's Health Imperative, Forward Together, Ipas, Sexuality Information and Education Council of the U.S. (SIECUS), HIV Law Project, National Women and AIDS Collective, and California Women's Law Center are not subsidiaries of any other corporation and no publicly held corporation owns ten percent or more of any *amici curiae* organization's stock.

/s/ Martha Jane Perkins  
Martha Jane Perkins

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## INTEREST OF THE AMICI<sup>1</sup>

The *amici curiae* are the National Health Law Program, American Public Health Association, National Family Planning & Reproductive Health Association, National Women's Health Network, National Latina Institute for Reproductive Health, National Asian Pacific American Women's Forum, Asian Americans Advancing Justice | AAJC, Asian Americans Advancing Justice | Los Angeles, Asian & Pacific Islander American Health Forum, Black Women's Health Imperative, Forward Together, Ipas, Sexuality Information and Education Council of the U.S. (SIECUS), HIV Law Project, National Women and AIDS Collective, and California Women's Law Center. While each *amicus* has particular interests, they collectively bring to the Court an in depth understanding of the standards of care and existing federal laws that address the use and coverage of preventive reproductive health services. The *amici* want to bring accurate information on these topics to the Court as it considers the legality of the requirements for preventive health care services under § 2713(a)(4) of the Public Health Service Act, added by the Patient Protection and Affordable Care Act (ACA).

## SUMMARY OF ARGUMENT

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<sup>1</sup> The parties consented to the filing of this brief. 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 intended to fund preparation or submission of this brief.

The ACA recognizes that preventive health services are critical to individual and community health. It accordingly requires new group health plans and health insurance issuers to cover such additional women’s preventive health care services as provided for in guidelines supported by the Health Resources and Services Administration (HRSA).<sup>2</sup> Regulations implementing this provision provide an accommodation for the group health plans of certain religious non-profit organizations.<sup>3</sup> After an organization self-certifies that it qualifies for the accommodation, women who participate in the organization’s health plan will have access to contraceptive coverage directly through a third-party insurer.<sup>4</sup> Thus, these laws accommodate sincerely held religious beliefs while also recognizing that women have unique reproductive and gender specific health needs.

Well-established standards of medical care and prevailing federal laws and policies predating the ACA recognize that family planning services are essential preventive care for women. The contraceptive coverage requirement adds to these larger federal policies and seeks to ensure that health plans sold in the individual and small group markets cover essential preventive services for women.

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<sup>2</sup> See Patient Protection and Affordable Care Act (ACA), Pub. L. No. 111-148, § 1001, § 2713(a)(4), 124 Stat. 119, 131 (codified at 42 U.S.C. § 300gg-13(a)(4)).

<sup>3</sup> 45 C.F.R. § 147.131(b) (defining “eligible organization”).

<sup>4</sup> 45 C.F.R. § 147.131(c).

## ARGUMENT

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

This case concerns the ACA and United States Department of Health and Human Services' (HHS) requirement that most new health insurance plans cover women's preventive health services, including contraception.<sup>5</sup> This requirement is in accord with accepted standards of medical care recognized by various professional medical academies and associations.

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.'"<sup>6</sup> Standards are based on "information from clinical experience that has met some established set of validity, and the appropriate standard is determined according to the requirements of the

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<sup>5</sup> See *id.*; 45 C.F.R. § 147.130(a)(1); U.S. Dep't of Health & Human Servs. (HHS), Health Res. & Servs. Admin., *Women's Preventive Services: Required Health Plan Coverage Guidelines*, <http://www.hrsa.gov/womensguidelines> (last visited Apr. 21, 2014).

<sup>6</sup> Am. Med. Ass'n (AMA) Council on Ethical & Judicial Affairs, *Report of the Council on Ethical & Judicial Affairs 12-A-04*, at 3 (2004) (footnote omitted) (citations omitted) (defining standard of care in context of medical testimony in legal proceedings).

intervention and clinical circumstance.”<sup>7</sup> 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 their development.<sup>8</sup>

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 of Family Planning, the American Academy of Pediatrics (AAP), the Society for Adolescent Medicine, the AMA, the American Public Health 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.”<sup>9</sup> For example, ACOG recommends that women have

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<sup>7</sup> LeighAnne Olsen et al., *The Learning Healthcare System: Workshop Summary (IOM Roundtable on Evidence-Based Medicine)* app. D 353, 354 (July 2011) (defining evidence).

<sup>8</sup> Nat’l Health Law Program, *Health Care Refusals: Undermining Quality Care for Women* 8 (2010) (defining standard of care).

<sup>9</sup> See Inst. of Med. (IOM) of the Nat’l Acads., *Clinical Preventive Services for Women: Closing the Gaps* 104 (2011) (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

access to family planning services.<sup>10</sup> 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.<sup>11</sup> The APHA has endorsed universal access to contraception for over thirty years.<sup>12</sup>

Similarly, the United States Centers for Disease Control and Prevention's (CDC) Agency for Toxic Substances and Diseases Registry concludes that preconception (before pregnancy) and inter-conception (between pregnancies) care should include family planning counseling along with health insurance coverage of contraceptives, because, among other things, this coverage can reduce the risk of maternal and infant mortality and pregnancy-related complications.<sup>13</sup> The AMA supports these CDC recommendations.<sup>14</sup> These recommendations are particularly important for women of color who disproportionately experience chronic health

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(2006) (discussing practice guidelines)).

<sup>10</sup> See, e.g., Am. Cong. of Obstetricians & Gynecologists (ACOG), *Technical Bulletin No. 205, Preconception Care*, 50 INT'L J. OF GYNECOLOGY & OBSTETRICS 201 (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).

<sup>11</sup> Michael C. Lu et al., *Recommendations for Preconception Care*, 76 AM. FAMILY PHYSICIAN 397, 399-400 (2007).

<sup>12</sup> Am. Pub. Health Ass'n, *Population: Family Planning as an Integral Part of Health Services*, Pol. No. 7518 (Jan. 1, 1975).

<sup>13</sup> Johnson et al., *supra* note 9, at 14, 17, 19-20.

<sup>14</sup> AMA House of Delegates, Policy No. H-425.976 (aff'd 2007).

conditions such as diabetes, heart disease, and obesity, all of which may be exacerbated by pregnancy.<sup>15</sup> In particular, these conditions underlie complications related to pregnancy or childbirth that contribute to the disproportionate maternal mortality rate among African American women.<sup>16</sup>

AAP and ACOG further recommend that every visit with a woman's clinician include a reproductive health screen and related counseling.<sup>17</sup> 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.<sup>18</sup> The discussion between the woman and her clinician is to "assist the [woman] in identifying the most appropriate and effective method for her" needs.<sup>19</sup>

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

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<sup>15</sup> See generally, Kaiser Family Found., *Putting Women's Health Care Disparities on the Map: Examining Racial and Ethnic Disparities at the State Level* (2009).

<sup>16</sup> See generally, D. Goffman et al., *Predictors of Maternal Mortality and Near-Miss Morbidity*, 27 J. PERINATOLOGY 597 (2007) (discussing racial disparities in maternal outcomes).

<sup>17</sup> Am. Acad. of Pediatrics (AAP) & ACOG, *Guidelines for Perinatal Care* 101 (7th ed. 2012); see also ACOG Comm. on Gynecologic Practice, *supra* note 10 (referring to guidelines for perinatal care and women's health care).

<sup>18</sup> See AAP & ACOG, *supra* note 17, at 101.

<sup>19</sup> *Id.*



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 pregnancies at least two years apart so that her body can properly recover.<sup>20</sup> 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 a significantly higher risk of other complications.<sup>21</sup> Research also shows that short birth intervals are associated with higher than average rates of low birth weight and neonatal death.<sup>22</sup> Thus, the professional associations, including the AMA and ACOG, recommend that women have access to contraceptive counseling and services, which will enable them to appropriately space their pregnancies.<sup>23</sup>

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

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<sup>20</sup> Cicley Marston, World Health Org., *Report of a WHO Technical Consultation on Birth Spacing, Geneva, Switzerland, 13-15 June 2005*, at 2 (2007).

<sup>21</sup> Thomas Gellhaus, Statement of ACOG to the U.S. Senate, Comm. on Health, Educ., Labor & Pensions, Pub. Health Subcomm: Safe Motherhood (Apr. 25, 2002).

<sup>22</sup> 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*, 332 N. ENG. J. MED. 69, 69 (1995) (citing studies).

<sup>23</sup> See discussion *supra* pp. 1-7.

Access to contraception is critical for 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.<sup>24</sup>

Approximately 11.7 million prescriptions for drugs, which the United States 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.<sup>25</sup> Approximately 5.8% of pregnancies in the United States are exposed to Category D or X drugs.<sup>26</sup> Multiple studies recommend that women of reproductive age who are taking these drugs use a reliable form of

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<sup>24</sup> 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, 292 (2010); Susan E. Andrade et al., *Prescription Drug Use in Pregnancy*, 191 AM. J. OBSTETRICS & GYNECOLOGY 398, 406 (2004).

<sup>25</sup> 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); Eleanor B. Schwarz et al., *Prescription of Teratogenic Medications in United States Ambulatory Practices*, 118 AM. J. MED. 1240, 1240-41 (2005).

<sup>26</sup> Eisenberg et al., *supra* note 24, at 291.

contraception to prevent pregnancy.<sup>27</sup> For example, Isotretinoin, a drug used to treat severe cystic acne, can cause multiple fetal impairments.<sup>28</sup> The FDA requires that women of reproductive age who are taking this drug agree to use two forms of contraception.<sup>29</sup> Iodine 131, which is used to treat hyperthyroidism and cancer, is another example of a drug for which pregnancy is contraindicated because it may destroy the developing fetus.<sup>30</sup> ACOG recommends that women taking Iodine 131 avoid pregnancy.<sup>31</sup>

**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.<sup>32</sup> African American women have twice the age standardized rate of fatal incidence of cardiovascular disease as white women.<sup>33</sup> Hispanic and non-Hispanic

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<sup>27</sup> See, e.g., *id.* at 291-92; Schwarz et al., *Documentation of Contraception*, *supra* note 25, at 374-75.

<sup>28</sup> Ctrs. for Disease Control & Prevention (CDC), *Accutane®--Exposed Pregnancies*, 49 MORBIDITY & MORTALITY WKLY. REPT. 28, 28 (2000).

<sup>29</sup> 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> (last visited Apr. 21, 2014).

<sup>30</sup> ACOG on Practice Bulletins, *Practice Bulletin No. 37: Clinical Management Guidelines for Obstetrician—Gynecologists, Thyroid Disease in Pregnancy* (2002).

<sup>31</sup> *Id.*

<sup>32</sup> CDC, *Women and Heart Disease Fact Sheet* (Aug. 2013), [http://www.cdc.gov/dhdsdp/data\\_statistics/fact\\_sheets/docs/fs\\_women\\_heart.pdf](http://www.cdc.gov/dhdsdp/data_statistics/fact_sheets/docs/fs_women_heart.pdf) (last visited Apr. 21, 2014).

<sup>33</sup> Monika M. Safford et al., *Association of Race and Sex with Risk of Incident*

Black women are also more likely to have multiple risk factors for heart disease, including high blood pressure, diabetes, and obesity.<sup>34</sup> There are a number of cardiac conditions, like valvular heart lesions, that are poorly tolerated given the physiological changes brought about during pregnancy.<sup>35</sup>

The American College of Cardiology and the American Heart Association Task Force on Practice Guidelines have issued specific recommendations for preconception management of women with valvular heart disease.<sup>36</sup> These guidelines recommend that management include provision of information about contraception and maternal and fetal risks of pregnancy.<sup>37</sup> These professional associations recommend that clinicians counsel women with certain heart

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*Acute Coronary Heart Disease Events*, 308 J. AM. MED. ASS'N 1768, 1772 (2012).

<sup>34</sup> Elsa-Grace V. Giardina, M.D. et al., *The DHHS Office on Women's Health Initiative to Improve Women's Heart Health: Focus on Knowledge and Awareness Among Women with Cardiometabolic Risk Factors*, 20 J. WOMEN'S HEALTH 893, 898 (Nov. 6, 2011).

<sup>35</sup> 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).

<sup>36</sup> Robert O. Bonow et al., *Guidelines for the Management of Patients with Valvular Heart Disease: Executive Summary A Report 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, 1973 (1998).

<sup>37</sup> *Id.* at 1974.

conditions, including valvular heart disease, against pregnancy.<sup>38</sup> The decision of whether to use contraception is, however, ultimately left to the woman.<sup>39</sup>

**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.<sup>40</sup> An estimated 10-18% of nonpregnant women of reproductive age have some type of abnormal glucose tolerance that carries maternal and fetal risks if they become pregnant.<sup>41</sup> Pregestational diabetes mellitus is a type of diabetes in women that develops before they become pregnant.<sup>42</sup> Pregestational diabetes is observed in about one percent of all pregnancies.<sup>43</sup> The type 2 diabetes prevalence rate is higher for

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<sup>38</sup> Bonow et al., *2008 Focused Update Incorporated Into the ACC/AHA 2006 Guidelines for the Management of Patients With Valvular Heart Disease*, *supra* note 35, at e598-99.

<sup>39</sup> *See, e.g.*, AAP & ACOG, *supra* note 17, 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.”).

<sup>40</sup> CDC, *Diabetes and Pregnancy* (Sept. 4, 2012), <http://www.cdc.gov/pregnancy/diabetes.html> (last visited Apr. 21, 2014).

<sup>41</sup> Thomas Buchanan, *Pregnancy in Preexisting Diabetes*, *DIABETES IN AM.* 719, 720 (Nat’l Diabetes Data Group et al., eds., 2d ed. 1995).

<sup>42</sup> CDC, *Diabetes and Pregnancy*, *supra* note 40.

<sup>43</sup> ACOG Comm. on Practice Bulletins, *Practice Bulletin No. 60: Pregestational Diabetes Mellitus*, *105 OBSTETRICS & GYNECOLOGY* 675, 675 (2005).

women of color.<sup>44</sup> Moreover, “compared with non-Hispanic white adults, the risk of diagnosed diabetes was 18 percent higher among Asian Americans, 66 percent higher among Hispanics/Latinos, and 77 percent higher among non-Hispanic blacks.”<sup>45</sup> Latinas also have higher rates of gestational diabetes than non-Hispanic white women, which puts them at greater risk for type 2 diabetes later in life.<sup>46</sup>

The failure to manage glucose levels during and before pregnancy can lead to serious complications and harm maternal and infant health.<sup>47</sup> For example, women with poorly controlled pregestational diabetes are at an increased risk of hypoglycemia, blindness, complications from chronic hypertension, and life-threatening complications from coronary heart disease.<sup>48</sup> 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

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<sup>44</sup> U.S. Dep’t of Health & Human Servs. (HHS), Nat’l Diabetes Info. Clearinghouse, *Diabetes Overview*, <http://diabetes.niddk.nih.gov/dm/pubs/overview/#who> (last visited Apr. 21, 2014); Ann S. Barnes & Stephanie A. Coulter, *The Epidemic of Obesity and Diabetes: Trends and Treatments*, 38 TEX. HEART INST. J. 142, 142 (2011).

<sup>45</sup> HHS, Nat’l Diabetes Info. Clearinghouse, *National Diabetes Statistics, 2011* (rev. Sept. 9, 2013), <http://diabetes.niddk.nih.gov/dm/pubs/statistics/#Racial> (last visited Apr. 21, 2014).

<sup>46</sup> Office on Women’s Health, *Minority Women’s Health: Diabetes* (updated May 18, 2010), <http://womenshealth.gov/minority-health/latinas/diabetes.html> (last visited Apr. 21, 2014).

<sup>47</sup> ACOG Comm. on Practice Bulletins, *Practice Bulletin No. 60*, *supra* note 43, at 676-77.

<sup>48</sup> *Id.* at 677-78.

pregnant women with type 1 diabetes.<sup>49</sup> The failure to manage glucose during preconception has been linked to malformations in infants and spontaneous abortion.<sup>50</sup>

The American Diabetes Association (ADA) and ACOG have issued standards of practice guidelines for preconception care for women with pregestational diabetes. According to the ADA, “planned pregnancies greatly facilitate preconception diabetes care.”<sup>51</sup> The ADA standards of care for women with diabetes with childbearing potential include: (1) “use of effective contraception at all times, unless the patient is in good metabolic control and actively trying to conceive” and (2) counseling about the risk of fetal impairment associated with unplanned pregnancies and poor metabolic control.<sup>52</sup> 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.<sup>53</sup>

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<sup>49</sup> E. Albert Reece et al., *Pregnancy in Women with Diabetic Nephropathy*, UptoDate (Dec. 3, 2012).

<sup>50</sup> Am. Diabetes Ass’n (ADA), *Preconception Care of Women with Diabetes*, 26 DIABETES CARE S91, S91 (2003).

<sup>51</sup> ADA, *Standards of Medical Care in Diabetes – 2006*, 36 DIABETES CARE S11, S44 (2013).

<sup>52</sup> *Id.*

<sup>53</sup> ACOG Comm. on Practice Bulletins, *Practice Bulletin No. 60*, *supra* note 43, at 681.

**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 autoimmune disorder, which can affect multiple parts of the body, including skin, joints, blood, and kidneys and that has multiple end-organ involvement.<sup>54</sup> Often called a “woman’s disease,” nine out of ten people with lupus are women.<sup>55</sup> The incidence rate for lupus is two to three times higher for African American women than for Caucasian women.<sup>56</sup> Lupus is also more common in women of Latina, Asian, and Native American descent.<sup>57</sup> Women with lupus who become pregnant face particularly increased risks of health complications.<sup>58</sup> A large review of United States hospital data found that the risk of maternal death for women with lupus is twenty times the risk for pregnant women without lupus.<sup>59</sup> Women with

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<sup>54</sup> HHS, Office on Women’s Health, *Lupus: Frequently Asked Questions* 1-2 (June 13, 2011), <http://www.womenshealth.gov/publications/our-publications/fact-sheet/lupus.pdf> (last visited Apr. 21, 2014).

<sup>55</sup> *Id.* at 2.

<sup>56</sup> *Id.*

<sup>57</sup> Nat’l Inst. of Arthritis & Musculoskeletal & Skin Diseases, *Handout on Health: Systemic Lupus Erythematosus* (2013), [http://www.niams.nih.gov/Health\\_Info/Lupus/](http://www.niams.nih.gov/Health_Info/Lupus/) (last visited Apr. 21, 2014).

<sup>58</sup> *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. OBSTETRICS & GYNECOLOGY. 127.e1, 127.e3 (2008).

<sup>59</sup> Clowse et al., *supra* note 58, at 127.e3.



lupus are three to seven times more likely to suffer from thrombosis, infection, renal failure, hypertension, and preeclampsia.<sup>60</sup>

The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) has issued a standard of care recommending that women with lupus take these health risks and complications into consideration in determining whether to become pregnant or to carry a pregnancy to term and that physicians counsel women to use contraception until their condition is under control.<sup>61</sup> Because of the multiple and life-threatening risks associated with lupus, NIAMS recommends that women delay pregnancy until there are no signs or symptoms of lupus.<sup>62</sup> 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.”<sup>63</sup> 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

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<sup>60</sup> *Id.* at 127e.1, e.3-e.4.

<sup>61</sup> Nat’l Inst. of Arthritis & Musculoskeletal & Skin Diseases, *Lupus: A Patient Care Guide for Nurses and Other Health Professionals* 45-47, Patient Info. Sheet Nos. 4-5 (3d ed. 2006).

<sup>62</sup> *Id.* at Patient Info. Sheet No. 11.

<sup>63</sup> *Id.* at Patient Info. Sheet No. 4.

lupus that using only barrier or behavior-based methods of contraception may not be appropriate.<sup>64</sup>

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.<sup>65</sup> HHS' decision to adopt the IOM's recommendation that women receive coverage for all FDA-approved methods of contraception free of cost-sharing comports with well-established standards of medical care.<sup>66</sup>

## **II. Contraceptive coverage is widely required through federal laws and policies pre-dating the ACA.**

The ACA and HHS coverage provisions reflect a long history of federal legislation which requires coverage of preventive contraceptive counseling, services, and supplies. In 1973, Congress enacted the Health Maintenance Organization (HMO) Act to encourage the delivery of health care through the

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<sup>64</sup> CDC, *U.S. Medical Eligibility Criteria for Contraceptive Use*, 2010, 59 MORBIDITY & MORTALITY WKLY. REPT. 4, 6 (2010).

<sup>65</sup> 42 U.S.C. § 300gg-13(a)(4).

<sup>66</sup> See 45 C.F.R. § 147.130(a)(1); HHS, Health Res. & Servs. Admin., *supra* note 5.

HMO model.<sup>67</sup> 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.<sup>68</sup> The HMO Act identifies basic health services that HMOs must provide.<sup>69</sup> “Basic health services” include “family planning services.”<sup>70</sup>

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 United States government.<sup>71</sup> The United States Office of Personnel Management contracts with qualified private insurance carriers to offer health care plans through the FEHB program.<sup>72</sup>

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<sup>67</sup> Health Maintenance Organization Act of 1973, Pub. L. No. 93-222, § 1, 87 Stat. 914, 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”).

<sup>68</sup> 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).

<sup>69</sup> 42 U.S.C. § 300e-1.

<sup>70</sup> 42 U.S.C. §§ 300e-1(1)(H)(iv) (defining “basic health service”), 300e (requiring HMO to cover “basic and supplemental health services”).

<sup>71</sup> *See* 5 U.S.C. §§ 8901-8914 (health insurance for government employees), 8905(a)-(b) (defining eligible persons).

<sup>72</sup> *Id.* § 8902; *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),

As part of the Omnibus Consolidated and Emergency Supplemental Appropriations Act of 1999, Congress approved a “contraceptive equity provision” requiring most FEHB plans to cover contraception.<sup>73</sup> Accordingly, the United States Office of Personnel Management requires all FEHB plans to cover the full range of FDA-approved contraceptive drugs and devices.<sup>74</sup> As amended in 1998, the FEHB program includes specifically enumerated religious health plans that do not have to cover contraception, and authorizes inclusion of future plans objecting to such coverage “on the basis of religious beliefs.”<sup>75</sup> However, the decision of whether to take up contraceptive coverage is left to the employee, who can choose from up to 300 plans, most of which cover contraception.<sup>76</sup>

Federal legislation regulating 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

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<http://www.opm.gov/feddata/factbook/> (last visited Apr. 21, 2014).

<sup>73</sup> Omnibus Consolidated & Emergency Supplemental Appropriations Act of 1999, Pub. L. No. 105-277, § 656(a), 112 Stat. 268, 530 (1998).

<sup>74</sup> U.S. Office of Pers. Mgmt., Benefits Admin. Ltr. No. 98-418 (Nov. 6, 1998).

<sup>75</sup> Pub. L. No. 105-277, § 656(b), 112 Stat. 268, *supra* note 73; *see also* Cong. Research Servs., *Laws Affecting the Federal Employees Benefits Program (FEHBP)* (Feb. 13, 2013), <https://www.fas.org/sgp/crs/misc/R42741.pdf> (last visited Apr. 21, 2014).

<sup>76</sup> U.S. Office of Pers. Mgmt., *Federal Employees Health Benefits Program Patients’ Bill of Rights and the Federal Employees Health Benefits Program*, <http://www.opm.gov/insure/archive/health/billrights.asp#Choice> (last visited Apr. 21, 2014).

in the uniformed services by providing an improved and uniform program of medical and dental care for members and certain former members of those services, and for their dependents.”<sup>77</sup> 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).<sup>78</sup> 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.”<sup>79</sup> TRICARE provides health care benefits to active-duty service members, retirees and their families, and other beneficiaries from any of the seven services.<sup>80</sup> TRICARE offers all beneficiaries a range of FDA-approved methods of contraception, including intrauterine devices, diaphragms, prescription contraceptives, and surgical sterilization.<sup>81</sup>

Congress’ declaration of a national policy of “ensur[ing] the highest possible health status for Indians and urban Indians” also includes the requirement that

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<sup>77</sup> 10 U.S.C. § 1071.

<sup>78</sup> Pub. L. No. 85-861, § 1(25)(B), 72 Stat. 1450 (1958), amended by Pub. L. No. 89-614, § 2(1), 80 Stat. 862 (1966) (codified at 10 U.S.C. §§ 1071-1110b).

<sup>79</sup> 32 C.F.R. §§ 199.17(a), 199.3; 10 U.S.C. § 1073(2).

<sup>80</sup> 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).

<sup>81</sup> 32 C.F.R. § 199.4(e)(3); 10 U.S.C. § 1077 (preventive health care services for women includes pregnancy prevention).

health plans cover family planning services and supplies.<sup>82</sup> 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 . . . .”<sup>83</sup> Congress’ definition of “health promotion” includes programs for “reproductive health and family planning.”<sup>84</sup> According to the Indian Health Manual, IHS “provide[s] comprehensive family planning services to all eligible American Indian and Alaska Native men and women.”<sup>85</sup> This includes, “[a]ll available Food and Drug Administration (FDA) approved types of contraceptive (mechanical, chemical and natural) methods,” with the individual deciding the appropriate choice of method.<sup>86</sup>

Coverage of family planning services and supplies is also a requirement of Medicaid—the country’s largest public health insurance program covering approximately sixty million low-income people.<sup>87</sup> States participating in Medicaid receive significant federal funding in return for providing specified health coverage

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<sup>82</sup> 25 U.S.C. § 1602(1)-(2).

<sup>83</sup> 25 U.S.C. § 1621b(a).

<sup>84</sup> 25 U.S.C. § 1603(11)(G)(xix).

<sup>85</sup> HHS, Indian Health Serv., *Indian Health Manual* § 3-13.12B(1), <http://www.ihs.gov/ihs/index.cfm> (last visited Apr. 21, 2014).

<sup>86</sup> *Id.* at §§ 3-13.12F(2), 3-13.12B(1).

<sup>87</sup> *See* 42 U.S.C. § 1396d(a)(4)(C); *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.”); Kaiser Family Found., *Medicaid: A Primer* 1 (Mar. 2013).

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.<sup>88</sup>

The ACA's contraceptive coverage provision builds upon this existing body of federal law. 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.

## CONCLUSION

Standards of medical care recommend that women have access to contraception as a necessary part of critical preventive health care services. The contraceptive coverage provision at issue here makes this access possible by ensuring that health plans in the individual and small group market adequately cover services that ensure women's health and well-being. This Court should find for the Defendants-Appellants and uphold the contraceptive coverage provision.

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<sup>88</sup> 42 U.S.C. § 1396d(a)(4)(c); 42 C.F.R. § 441.20; *see* Ctrs. for Medicare & Medicaid Svcs. (CMS), *State Medicaid Manual* § 4270; CMS, *Dear State Medicaid Director* (July 2, 2010) (discussing family planning related services in context of new eligibility option under ACA § 2303).

Date: April 21, 2014

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## 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. 32(a)(7)(B) and 29(d), and that the total number of words in this brief is 4,722 words, according to the count of Microsoft Word, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

Date: April 21, 2014

/s/Martha Jane Perkins  
Martha Jane Perkins

## CERTIFICATE OF DIGITAL SUBMISSION

I hereby certify that with respect to the foregoing:

- (1) all required privacy redactions have been made per 10th Cir. R. 25.5;
- (2) the hard copies I will cause to be submitted to the Clerk of the Court are exact copies of the ECF submission;
- (3) the electronic submission has been scanned for viruses and is free of viruses.

Dated: April 21, 2014

/s/ Martha Jane Perkins  
Martha Jane Perkins

### **CERTIFICATE OF SERVICE**

I hereby certify that on April 21, 2014, I electronically filed the foregoing brief with the Clerk of the Court 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.

Date: April 21, 2014

/s/Martha Jane Perkins  
Martha Jane Perkins