

The Real War on Women: HHS Ignores World Health Organization classification of Mandated Combined Oral Contraceptives as "Carcinogenic to Humans"

The coercive HHS Mandate completely failed to address relevant evidence of significantly *increased* risks of cancers, stroke & heart attack.

BDF & LLDF Amicus Brief: Hormonal Contraceptives are not "Preventive" Healthcare

In consultation with medical advisors, **Bioethics Defense Fund (BDF)** and **Life Legal Defense Foundation (LLDF)** are speaking out in courts for religious liberty and women's health concerning drugs that are capable of being abortifacient.

1. The Religious Freedom

Restoration Act (RFRA) requires that when government action burdens religious liberty, it must be narrowly tailored to further a compelling governmental interest – here, an asserted interest in expanding access to women's "preventive" health services.

2. The Institute of Medicine report

adopted by HHS completely ignored the large body of relevant evidence showing that hormonal contraceptives **significantly increase risk of cancers, stroke, heart attack, and even HIV.**

3. Thus, our amicus brief shows that

(1) the Mandate violates the APA as being "arbitrary and capricious" for ignoring relevant evidence; and (2) the HHS Mandate fails RFRA because coercing religious objectors to fund drugs that **increase** risk of disease does not further the government interest in women's "preventive" healthcare.

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HHS didn't even try to balance these risks with the asserted benefits, not even mentioning that the **World Health Organization** classifies combined oral contraceptives as "**Group 1: Carcinogenic to Humans.**"¹

While women may experience different direct short-term side effects, all women are disserved by the HHS failure to address the long-term health risks:



ORAL CONTRACEPTIVE PILL RISKS

IGNORED BY HHS

HIGHER RISK OF STROKE & HEART ATTACK: **2 times** the risk of heart attack if no other risk factors, **12 times** the risk for smokers²; Nearly **3 times** the risk of stroke.³

HIGHER RISK OF BREAST CANCER: A 2009 study showed a more than **3 times** increased risk of the deadly triple-negative breast cancer.⁴ A meta-analysis shows a **44%** increased risk.⁵

HIGHER RISK OF CERVICAL CANCER: The NCI cites studies showing **3 times** increased risk among women using the Pill for 5 to 9 years, and **4 times** higher if 10 years or more.⁶

HIGHER RISK OF LIVER TUMORS/CANCER: Some studies show an increased risk of malignant liver tumors for those who take the pill for over 5 years, while others do not.⁷

INCREASED SUSCEPTIBILITY TO STIs & HIV: Women taking oral contraceptives are **2 times** more likely to be infected with the HPV virus⁸, and **60%** more likely to be infected with HIV.⁹

LONG-ACTING CONTRACEPTIVE RISKS

IGNORED BY HHS

DEPO-PROVERA®: This injectable has a black box warning on **loss of bone mineral density**¹⁰, and a major study reports a **doubled** risk of acquiring and transmitting **HIV**.¹¹

IMPLANON®: The manufacturer of this implant rod warns of **ectopic pregnancy** risks and "serious ...cases of **pulmonary emboli** (some fatal) and **strokes**."¹²

PARAGARD® COPPER IUD: Risks include **uterine perforation** and other malpositioning that can result in **increased bleeding** or pain, and injury or **damage to the surrounding organs**.¹³

MIRENA® IUD: This device releases a steroidal hormone into the uterine environment. Risks include **uterine perforation**, **ovarian cysts**, **pelvic inflammatory disease** & **irregular bleeding**.¹⁴

- **RISK OF INFERTILITY:** The Mirena manufacturer warns that "in the rare case" in which a woman conceives a "possible permanent loss of fertility may result."¹⁴



Read full amicus brief at www.BDFund.org/HHS_Mandate

¹ International Agency on Research of Cancer, 2007 Monograph 91. Combined estrogen-progestogen contraceptives and combined estrogen-progestogen menopausal therapy. Available at: <http://monographs.iarc.fr/ENG/Monographs/vol91/mon091.pdf>

² Tanis BC, et al. Oral contraceptives and the risk of myocardial infarction. *New England Journal of Medicine* 2001;345:1787-93.

³ Gillum, LA. Ischemic stroke risk with oral contraceptives. *JAMA* July 5 2000;284:72-78.

⁴ Dolle J, et al. Risk factors for triple negative breast cancer in women under the age of 45. *Cancer Epidemiol Biomarkers Prev* 2009;18(4):1157-65.

⁵ Kahlenborn C, et al. Oral contraceptive use as a risk factor for premenopausal breast cancer: A meta-analysis. 2006 *Mayo Clinic Proc* 2006;81(10):1290-1302.

⁶ National Cancer Institute: Oral Contraceptives and Cancer Risk (March 21 2012) citing Moreno V, Bosch FX, Munoz N, et al. Effect of oral contraceptives on risk of cervical cancer in women with human papillomavirus infection: the IARC multicentric case-control study. *Lancet* 2002; 359(9312):1085-1092.

⁷ *Id.*, citing La Vecchia C, Tavani A. Female hormones and benign liver tumours. *Digestive and Liver Disease* 2006; 38(8):535-536.

⁸ Franceschi S, et al. Genital warts and cervical neoplasia: an epidemiological study. *Br J Cancer* 1983;48:621-28.

⁹ Wang CC, et al. Risk of HIV infection in oral contraceptive pill users: a meta-analysis. *JAIDS* 1999;May 1 21(1):51-58.

¹⁰ FDA, Highlights of Prescribing Information: Depo-Provera, available at http://www.accessdata.fda.gov/drugsatfda_docs/label/2010/020246s036lbl.pdf.

¹¹ Heffron R., et al. Use of hormonal contraceptives and risk of HIV-1 transmission: a prospective cohort study. *Lancet Infect Dis* 2012; 12:19-26.

¹² Implanon® Warnings, available at <http://www.implanon-usa.com/en/HCP/learn-about-it/get-the-facts/warnings/index.asp>.

¹³ Braaten, K.P. et al., "Malpositioned IUDs: When you should intervene (and when you should not)." *OBG Management* 2012; 24(8):39-46, citing Bernacerraf, B.R. et al. "Three-dimensional ultrasound detection of abnormally located intrauterine contraceptive devices which are a source of pelvic pain and abnormal bleeding." *Ultrasound Obstet Gynecol* 2009; 34(1):110-115.

¹⁴ Mirena® Label, Warnings and Precautions; See also Uterine Perforation Risk from Mirena, available at <http://www.womens-health.co.uk/uterine-perforation-risk-from-mirena.html>.