

**The Meaning of “Spouse” and “Family”
in FDA’s Regulations after the Supreme
Court’s Ruling in *United States v. Windsor*—
Questions and Answers: Guidance for
Industry, Consumers, and FDA Staff**

**U.S. Department of Health and Human Services
Food and Drug Administration
Office of Policy, Office of the Commissioner**

April 2014

**The Meaning of “Spouse” and “Family”
in FDA’s Regulations after the Supreme
Court’s Ruling in *United States v. Windsor*—
Questions and Answers: Guidance for
Industry, Consumers, and FDA Staff**

Additional copies of this guidance are available from the Office of Policy, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Avenue, Silver Spring, MD 20993, or by calling 301-796-4830, or from the Internet at <http://www.fda.gov/RegulatoryInformation/Guidances/ucm389748.htm>.

**U.S. Department of Health and Human Services
Food and Drug Administration
Office of Policy
Office of the Commissioner
April 2014**

Table of Contents

I.	INTRODUCTION.....	1
II.	QUESTIONS AND ANSWERS.....	1
	<i>Q1: How does the Supreme Court’s United States v. Windsor decision affect FDA’s regulations?.....</i>	<i>1</i>
	<i>Q2: Do you have to live or intend to live in a state in which same-sex marriage is legal for FDA’s regulations using the terms “spouse” or “family” to apply to you?.....</i>	<i>1</i>
	<i>Q3: Which FDA regulations are affected by the Windsor decision?</i>	<i>2</i>

The Meaning of “Spouse” and “Family” in FDA’s Regulations after the Supreme Court’s ruling in *United States v. Windsor*— Questions and Answers: Guidance for Industry, Consumers, and FDA Staff

I. INTRODUCTION

On June 26, 2013, in *United States v. Windsor*, 133 S.Ct. 2675, the Supreme Court struck down as unconstitutional section 3 of the Defense of Marriage Act (DOMA). Using a question and answer format, we, FDA, are informing the public of our current thinking about the meaning of “spouse” or “family” in our regulations in light of this ruling.

FDA’s guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency’s current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited.

II. QUESTIONS AND ANSWERS

Q1: How does the Supreme Court’s United States v. Windsor decision affect FDA’s regulations?

A1: Section 3 of DOMA defined “marriage” and “spouse” to exclude same-sex spouses. Because the Supreme Court ruled this section unconstitutional, FDA need no longer exclude same-sex spouses from the definition of these terms. Consistent with the Department of Health and Human Service (HHS) policy, FDA will interpret the terms “spouse” and “family” in its regulations to include same-sex spouses.

Q2: Do you have to live or intend to live in a state in which same-sex marriage is legal for FDA’s regulations using the terms “spouse” or “family” to apply to you?

A2: No. We interpret “spouse” or “family” in our regulations to include any individuals of the same sex who are lawfully married and whose marriage is valid

in the state, territory or foreign nation where it took place. These terms also include same-sex spouses whose marriages are valid in the state, territory, or foreign nation where they live. This policy is consistent with a post-*Windsor* policy of treating same-sex marriages on the same terms as opposite-sex marriages to the greatest extent reasonably possible. By broadening the coverage of “spouse” and “family” to include same-sex spouses, it also advances the underlying goals of FDA’s regulations. For example, requiring clinical investigators to disclose the financial interests and arrangements of their same-sex spouses (see discussion of FDA Financial Disclosure by Clinical Investigators below) better ensures that conflicts of interests do not arise.

Q3: Which FDA regulations are affected by the Windsor decision?

A3: Because they use the terms “spouse” or “family,” six parts of FDA’s regulations are affected by the *Windsor* decision. Consistent with this decision and HHS policy, FDA now reads these terms to include same-sex spouses. The affected regulations are as follows:

- **FDA Freedom of Information Act (FOIA) program (21 CFR 20.44 (b)).** A “family member,” including a same-sex spouse, of an individual subject to an imminent threat may request expedited processing of a FOIA request.
- **FDA Human Subject Protection (21 CFR 50.3 (l), (m), 50.24(a)(6), (a)(7)(v), (b)).** “Family member” means, among other things, “spouse,” “brothers, sisters, and spouses of brothers and sisters,” and “any individual related by . . . affinity whose close association with the subject is the equivalent of a family relationship.” An exception from the requirement to obtain informed consent of research subjects exists if obtaining informed consent is not feasible and a legally authorized representative is not reasonably available. If feasible, an investigator must attempt to contact a subject’s family member, which can include a same-sex spouse, to ask whether he or she objects to the subject’s participation in the clinical investigation. Additionally, if a subject remains incapacitated and a subject’s legally authorized representative is not reasonably available, an Institutional Review Board (IRB) shall ensure that there is a procedure to inform a family member, which can include a same-sex spouse, that he or she may discontinue the subject’s participation at any time without penalty or loss of benefits to which the subject is otherwise entitled. If such a family member is told about the clinical investigation and the subject’s condition improves, the subject is also to be informed as soon as feasible. If a subject is entered into a clinical investigation with waived consent and the subject dies before a legally authorized representative or family member, which can include a same-sex spouse, can be contacted, information about the clinical investigation is to be provided to the

subject's legally authorized representative or such family member, if feasible.

- **FDA Financial Disclosure by Clinical Investigators (21 CFR 54.2(d)).** Part 54 of FDA's regulations requires disclosure of certain types of financial interests and arrangements involving a "clinical investigator" and defines "clinical investigator" to include the investigator's "spouse." Consistent with the *Windsor* decision and HHS policy, FDA now interprets Part 54 to require disclosure of certain financial interests and arrangements involving any clinical investigator's same-sex spouse.
- **Institutional Review Board for FDA-regulated Research (21 CFR 56.107(d)).** Each IRB must have at least one member who is not otherwise affiliated with the institution and is not part of the "immediate family," now including a same-sex spouse, of a person affiliated with the institution.
- **Qualified Expert Panels for Indexing New Animal Drugs (21 CFR 516.141(g)(2), (g)(3)).** Information required to be submitted to FDA and factors considered to prevent conflicts of interest in members of these expert panels include information relating to "spouses," including same-sex spouses.
- **Mammography Quality Standards Program (21 CFR 900.2(k)).** Mammography facilities must have systems for collecting and resolving consumer complaints. "Consumer" includes a patient or patient representative—for example, a "family member," including a same-sex spouse.