No. 13-354

IN THE
Supreme Court of the United States

KATHLEEN SEBELIUS, ET AL.,
Petitioners,

— v.—

HOBBY LOBBY STORES, INC., ET AL.,
Respondents.

ON WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS
FOR THE TENTH CIRCUIT

AMICUS CURIAE BRIEF OF CATHOLIC MEDICAL ASSOCIATION IN SUPPORT OF RESPONDENTS

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INTEREST OF *AMICUS*[1]

Amicus curiae is the Catholic Medical Association, a national non-profit organization comprised of approximately 2,000 members practicing in more than

[1] Pursuant to Supreme Court Rule 37.6, counsel for *amicus* certifies that this brief was not authored in whole or in part by counsel for any party, and no person or entity other than *amicus* or its counsel has made a monetary contribution to the preparation or submission of this brief. Pursuant to Rule 37.3(a), Petitioners have filed a letter of consent to the filing of this brief with the Clerk, and Respondents' letter of consent is filed with this brief.

75 medical specialties across the United States. The Catholic Medical Association helps to educate the medical profession and society at large about issues in medical ethics, including abortion and maternal health, through its annual conferences and quarterly journal, *The Linacre Quarterly*.

As Catholic physicians and medical professionals, the members of the Catholic Medical Association have a profound interest in providing the best health care to their patients and all Americans, including the unborn. Based on well-established biological and embryological understanding of human reproduction, *Amicus* believes that human life begins at fertilization. *Amicus* opposes Petitioner's requirement that Respondents and other employers provide drugs and devices that can operate post-fertilization by preventing implantation of existing human embryos in the endometrium, thereby terminating the pregnancy and killing the embryo.

SUMMARY OF ARGUMENT

Although the Court need not decide what "abortion" or "pregnancy" mean to decide this appeal, the Court should recognize that Petitioners' proffered definition of "pregnancy" as beginning at implantation is anomalous. As shown below, both science and the bulk of federal law treat fertilization and the presence of a human embryo as the beginning of pregnancy and human development. Any method preventing implantation of the human embryo thus results in an abortion.

Here, Respondents object to two types of intrauterine devices ("IUDs") and two so-called "emergency contraceptives" in pill form because they affect the endometrium or uterine lining and can prevent implantation of an already-existing human embryo. *See* Resp. Br. on Pet. for Cert. at 4–5.

Petitioners do not dispute that each of the objected-to "contraceptive methods" alters the endometrium and that each such method "may" prevent or "possibly" prevents implantation of an existing embryo. Pet. Br. at 9–10 n.4. Instead, Petitioners re-define "pregnancy" and argue that preventing the implantation of a human embryo in the endometrium does not terminate a "pregnancy" and therefore is not abortive. *Ibid.*

Petitioners contend that preventing an embryo from implanting in the endometrium does not terminate a pregnancy because they claim that federal law "defines pregnancy as beginning at implantation." *Ibid.* (citing 45 C.F.R. § 46.202(f)). Because pregnancy begins at implantation, according to Petitioners, any device or drug that prevents implantation merely prevents pregnancy and is, therefore, a contraceptive and not an abortifacient. But section 46.202's definition is not consistent with the scientific understanding of the earliest stages of human development. Indeed, it ignores completely the process of fertilization and existence of a human embryo prior to implantation. In the face of well-established science, Petitioners' semantic argument based on a federal regulation does not alleviate the religious and moral concerns of Respondents.

Moreover, Petitioners cherry pick section 46.202(f)'s definition of "pregnancy" from among numerous other federal regulations addressing pregnancy and the earliest stages of human development. Though not cited by Petitioners, federal law elsewhere focuses on the presence of an embryo, regardless of implantation, to determine whether a woman is pregnant or whether a separate organism exists. The focus on the presence of an embryo in those regulations is for good reason. The biological evidence is that a unique organism—the

embryo—exists upon fertilization prior to the embryo's implantation in the endometrium.

Petitioners cannot dismiss Respondents' religious objections by resorting to semantics and re-defining "pregnancy" to avoid the reality that the objected-to devices and drugs can abort an existing embryo by preventing implantation. Moreover, the focus of federal regulations—which Petitioners have ignored—on the presence of an embryo to determine pregnancy, demonstrates that a single regulation defining pregnancy as "implantation" does not end the debate. Respondents' religious objections to providing the specified IUDs and drugs because they may be abortive are well grounded in science and supported by federal law.

Finally, Petitioners' requirement that Respondents provide coverage for these abortifacient drugs and devices or face severe fines violates federal law. As alleged in Respondents' complaint, the Weldon Amendment prohibits Petitioners from discriminating against Respondents' insurance plan by subjecting Respondents to draconian fines simply because they will not provide, pay for, or provide coverage of abortions. Respondents should not be permitted to trample over Congress's explicit recognition that religious objections to abortion are legitimate and worthy of accommodation simply by ignoring the existence of the embryo—an individual human life—prior to implantation.

ARGUMENT

I. FERTILIZATION PRIOR TO IMPLANTATION MARKS THE EXISTENCE OF A HUMAN EMBRYO.

To avoid the religious and moral implications of terminating a pregnancy through the devices and drugs in contention, Petitioners simply redefine pregnancy as

beginning after those devices and drugs have acted to end the pregnancy. Specifically, Petitioners contend that pregnancy begins upon implantation of a "fertilized egg in the uterus."[2] Pet. Br. at 9–10 n.4. If pregnancy begins upon implantation, then any device or drug that prevents implantation of a "fertilized egg in the uterus"—as the objected-to devices and drugs indisputably can—prevents pregnancy rather than terminating pregnancy. *Ibid*. Identifying implantation as the commencement of pregnancy ignores the long-established biological and embryological evidence that a distinct organism—a human embryo—exists well before implantation in the uterus.

Human existence is a continuum marked by a distinct beginning and ending with death. *See* Maureen L. Condic, *When Does Human Life Begin? A Scientific Perspective* 12 (The Westchester Institute for Ethics & the Human Person Oct. 2008), http://bdfund.org/wordpress/wp-content/uploads/2012/06/wi_whitepaper_life_print.pdf (last visited January 25, 2014). There can be no dispute that human life begins with fertilization and the formation of the human embryo. "Human development begins at fertilization when a male gamete or sperm (spermatozoon) unites with a female gamete or oocyte (ovum) to form a single cell—a zygote. This highly specialized, totipotent cell marked the beginning of each of us as a unique individual." Keith L. Moore & T.V.N. Persaud, *The Developing Human: Clinically Oriented Embryology* 16 (7th ed. 2003). "[T]he male and female sex cells or

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[2] A "fertilized egg," of course, is an embryo since by definition fertilization means the "egg" and sperm have united to become the zygote or embryo. Bruce M. Carlson, *Human Embryology and Developmental Biology* 3 (1st ed. 1994).

gametes . . . will unite at fertilization to initiate the embryonic development of a new individual." William J. Larsen, *Human Embryology* 1 (3d ed. 2001); *see* Ronan O'Rahilly & Fabiola Müller, *Developmental Stages in Human Embryos* 9 (1987) ("Embryonic life commences with fertilization.").

Even the National Institutes of Health defines "fertilization" as "the process of union of two gametes whereby the somatic chromosome number is restored and *the development of a new individual is initiated*." National Institutes of Health, *Medline Plus Merriam-Webster Medical Dictionary* (2013), www.merriam-webster.com/medlineplus/fertilization (last visited January 26, 2014) (emphasis added); *see also* O'Rahilly & Müller, at 9 ("Despite the small size (ca. 0.1mm) and weight (ca. 0.004 mg) of the organism at fertilization, the embryo is 'schon ein individual-spezifischer Mensch.'" (translated from German to English: "already an individual-specific human")).

Fertilization itself is a process that "begins when a spermatozoon makes contact with an oocyte or its investments and ends with the intermingling of maternal and paternal chromosomes at metaphase of the first mitotic division of the zygote." O'Rahilly & Müller, at 9; *see also* Moore & Persaud, at 31 ("Fertilization is a complex sequence of coordinated molecular events that begins with contact between a sperm and an oocyte . . . and ends with the intermingling of maternal and paternal chromosomes at metaphase of the first mitotic division of the zygote, a unicellular embryo."); Larsen, at 1–2. A zygote is the cell that "results from the union of an oocyte and a sperm during fertilization. A zygote is the beginning of a new human being (i.e., an embryo)." Moore & Persaud, at 2.

Because it is a process, scientific debate exists regarding when in the process of fertilization—at the beginning or the end—the human embryo comes into existence. *Amicus* contends, and the great weight of evidence supports, that the distinct human organism exists at the beginning of the process at the "'moment' of sperm-egg fusion." Condic, at 5–7.

However, even if the embryo is not considered to exist until the end of the fertilization process, when the zygote begins to divide, the embryo still exists for five or six days before implantation takes place. *See* Larsen, at 21–22; Moore & Persaud, at 37. "Fertilization requires probably slightly longer than 24 hours in primates" and "takes place normally in the ampulla of the uterine tube." O'Rahilly & Müller, at 9; Moore & Persaud, at 31–32 ("The usual site of fertilization is the ampulla of the uterine tube, its longest and widest part. . . . Although fertilization may occur in other parts of the tube, it does not occur in the uterus. . . . The fertilization process takes about 24 hours."). While fertilization occurs in the fallopian tube in the first 24 hours after the sperm and oocyte unite, implantation of the embryo in the endometrium does not occur until five or six days later. *See* Larsen, at 21–22; Moore & Persaud, at 37.

Since the embryo exists at least five to six days before implantation, efforts to prevent implantation—including the particular IUDs and drugs at issue here—are necessarily efforts to destroy the embryo. "The administration of relatively large doses of estrogens ("morning-after pills") for several days, beginning shortly after unprotected sexual intercourse, usually does not prevent fertilization but often prevents implantation of the blastocyst." Moore & Persaud, at 52. Likewise, IUDs that "contain progesterone that is slowly released and interferes with the development of the

endometrium so that implantation does not usually occur." *Ibid.* Indeed, because the drugs in contention

> *prevent implantation, not fertilization* . . . . they should not be called contraceptive pills. Conception occurs but the blastocyst does not implant. It would be more appropriate to call them "contraimplantation pills." Because the term *abortion* refers to a premature stoppage of a pregnancy, the term *abortion* could be applied to such an early termination of pregnancy.

Id. at 504.

Defining "pregnancy" as beginning at implantation ignores the process of fertilization and the existence of the embryo prior to implantation. *See* Carlson, at 3 ("Human pregnancy begins with the fusion of an egg and a sperm . . . . [T]he fertilized egg, now properly called an embryo, must make its way into the uterus, where it sinks into the uterine lining (implantation)."). Even if "pregnancy" has not commenced until implantation, a human embryo exists. By preventing implantation, that embryo is killed. This is the crux of Respondents' religious and moral objection to providing drugs or devices that prevent implantation. The semantics of defining "pregnancy" cannot alter the biological evidence or, more importantly, alleviate Respondents' religious and moral objection to abortion, including abortion by preventing implantation.

II. THE TERM "IMPLANTATION" IS ANOMALOUS TO THE CODE OF FEDERAL REGULATIONS' DEFINITION AND UNDERSTANDING OF PREGNANCY.

In their effort to avoid the religious and moral implications of terminating a pregnancy by preventing the implantation of an existing human embryo,

Petitioners rely on the definition of "pregnancy" in Title 45 of the Code of Federal Regulations pertaining to protections for pregnant women who are subjects in research supported by the Department of Health and Human Services. Pet. Br. at 9–10 n.4. (citing 45 C.F.R. § 46.202(f)); *see* 45 C.F.R. § 46.201(a). But that definition does not conclusively establish that the devices and drugs in contention are not abortive under federal law. Petitioners are wrong to suggest that federal regulations recognize pregnancy or individual life as existing only post-implantation.

Significantly, for purposes of the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC), the Code of Federal Regulations defines "Pregnant women" as "women determined to have one or more embryos or fetuses in utero." 7 C.F.R. § 246.2. These "Pregnant Women" are categorically eligible for benefits under the program, provided that other eligibility criteria are met. *Ibid.*; *id.* § 246.7(c). This same definition of "Pregnant Women" appears again in 32 C.F.R section 199.23(b)(23), which contains guidelines and policies for delivery and administration of the WIC Overseas Program.

Nothing in the WIC regulations restricts eligibility to only those women whose embryos have already implanted in the uterine wall. On the contrary, a State agency "opting to require proof of pregnancy" may "issue benefits to applicants who claim to be pregnant" even if they have no "visibly noticeable" pregnancy conditions, provided that documentation of the pregnancy is received within a reasonable period of time. 7 C.F.R. § 246.7(c)(2)(ii). Such conditions, of course, would not be visible prior to implantation. The Code likewise requires that for "a pregnant woman, the State agency must count each embryo or fetus in utero as a household

member in determining if the household meets the income eligibility standards" for the Commodity Supplemental Food Program. *Id.* § 247.9(b)(3).

Elsewhere in the Code, regulations use the term "conception"—not "implantation"—as the demarcation of life for purposes of the Code's health and safety protections. In the Nuclear Regulatory Commission's Standards for Protection against Radiation, an "embryo/fetus" is defined as "the developing human organism from conception until the time of birth." 10 C.F.R. § 20.1003. Those Standards explicitly protect the "embryo/fetus" from excessive radiation "during the entire pregnancy." *Id.* § 20.1208(a). The duration of the pregnancy is a function of the presence of an "embryo/fetus," which is the "developing human organism from conception until the time of birth." *Ibid.*; *id.* § 20.1003. Likewise, the Standards for Internal and External Exposure to radiation articulated by the Department of Energy grant similar protections to the "embryo/fetus from the period of conception to birth," with no mention of "implantation." *Id.* § 835.206(a). And the regulations governing the States' various Children's Health Insurance Programs straightforwardly define "child" as "an individual under the age of 19 including the period *from conception* to birth." 42 C.F.R. § 457.10 (emphasis added).

Other federal regulations pertaining to the protection of human research subjects focus on the presence of an embryo to establish pregnancy, again without reference to implantation. For example, to obtain legally sufficient informed consent from a woman who will be a research subject in a government study, the woman must receive a "statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or

may become pregnant) which are currently unforeseeable." *See* 15 C.F.R. § 27.116(b)(1) (applicable to "all research involving human subjects conducted, supported or otherwise subject to regulation by any federal department or agency," *id.* § 27.101(a)); *see also, e.g.,* 16 C.F.R. § 1028.116(b)(1) (same for the Consumer Product Safety Commission); 21 C.F.R. § 50.25(b)(1) (same for the Food and Drug Administration); 22 C.F.R. § 225.116(b)(1) (same for the Agency for International Development); 32 C.F.R. § 219.116(b)(1) (same for the Department of Defense). Whether the subject is pregnant depends on the presence of an embryo or fetus, not an implanted embryo.

To the extent Petitioners would elide the distinction between "conception" and "implantation," section 46.202 of Title 45 forecloses that argument. There, "Fetus" is defined as "the product of conception from implantation until delivery," meaning that conception is a distinct and necessary precursor to implantation. 45 C.F.R. § 46.202(c). Neither can section 46.202's notion that pregnancy begins with "implantation" be reconciled with other federal regulations focused on the presence of an embryo. In normal usage, the "conception" and "fertilization" are synonymous. *See, e.g.*, Philip G. Peters, Jr., *The Ambiguous Meaning of Human Conception*, 40 U.C. Davis L. Rev. 199, 202 (2006). The "product of conception" or fertilization is the embryo, which exists prior to implantation, both as a matter of biological fact and under section 46.202's definition of "Fetus."

III. FEDERAL LAW PROHIBITS DISCRIMINATION AGAINST RESPONDENTS BECAUSE OF THEIR OPPOSITION TO ABORTION.

Petitioners' requirement that Respondents provide coverage for abortifacient drugs and devices or face severe fines violates federal law. Congress has recognized that opposition to abortion is a matter of conscience worthy of statutory protection. *See* Weldon Amendment of the Consolidated Appropriations Act, 2012, Pub. L. No. 112-74, div. F, tit. V, § 507(d)(1), 125 Stat. 786, 1111 (2011). Accordingly, it enacted the Weldon Amendment to the Consolidated Appropriations Act, 2012, which prohibits the use of funds by a "Federal agency or program" if that agency or program discriminates against "any institutional or individual health care entity" because the "health care entity does not provide, pay for, provide coverage of, or refer for abortions." *Ibid.*

The Amendment defines "health care entity" broadly to include "a health insurance plan, or any other kind of health care facility, organization, or plan." *Id.* § 507(d)(2). Because Respondents self-fund their employee insurance plan, Resp. Br. on Pet. for Cert. at i, 3, they fall within the ambit of the Weldon Amendment as an "insurance plan," and Petitioners may not discriminate against that plan by imposing ruinous fines simply because Respondents do not "provide, pay for, provide coverage of . . . abortions." Respondents have accordingly raised an Administrative Procedure Act claim—not before the Court on this appeal—based on the Weldon Amendment. J.A. 163.

Although the Weldon Amendment does not define "abortion," the prevention of the implantation of a human embryo by drug or device is, as noted by Professors Moore and Persaud, an abortion. Moore &

Persaud, at 504. Moreover, where a term is undefined, it should be given its ordinary meaning, which is informed by contemporaneous dictionaries. *See Taniguchi v. Kan Pacific Saipan, Ltd.*, 132 S. Ct. 1997, 2002 (2012) ("When a term goes undefined in a statute, we give the term its ordinary meaning.").

Stedman's Medical Dictionary defines "abortion" as the "[e]xpulsion from the uterus of *an embryo* or fetus [before] viability." *Stedman's Medical Dictionary* 4 (28th ed. 2006) (emphasis added). There is no requirement that the "expulsion" occur after implantation. The National Institutes of Health defines "abortion" as "the termination of a pregnancy after, accompanied by, resulting in, or closely followed by *the death of the embryo* or fetus." National Institutes of Health, *Medline Plus Merriam-Webster Medical Dictionary* (2013), http://www.merriam-webster.com/medlineplus/abortion (last visited January 26, 2014) (emphasis added). Again, implantation is not necessary to have an abortion, only the "death of the embryo," which occurs when drugs or devices alter the normal course and prevent implantation of the embryo. Under both definitions, drugs or devices that prevent implantation are abortive because they result in the "expulsion" and "death" of the embryo.

Another medical dictionary defines "pregnancy" as the "condition of having *a developing embryo* or fetus in the body, after union of an ovum and spermatozoon." *Dorland's Illustrated Medical Dictionary* 1500 (31st ed. 2007) (emphasis added); *see* National Institutes of Health, *Medline Plus Merriam-Webster Medical Dictionary* (2013), http://www.merriam-webster.com/medlineplus/pregnant (last visited January 26, 2014) ("containing a developing embryo, fetus, or unborn offspring within the body"). On this definition,

abortion—the termination of pregnancy—is the termination of the "condition of having a developing embryo or fetus in the body." Preventing the implantation of the embryo in the endometrium indisputably ends the condition of having a developing embryo in the body.

Under these generally recognized definitions and the review of scientific literature addressed in Part I, four of the contraceptive-coverage mandate's required drugs and devices may cause abortion. Because the Respondents have a self-funded insurance plan that does not cover abortifacients, the Weldon Amendment prohibits discrimination against Respondents' insurance plan in the form of the severe fines proposed by Petitioners. The contraceptive-coverage requirement therefore violates federal law, and the anomalous definition of pregnancy in 45 C.F.R. § 46.202(f) provides no excuse. Petitioners cannot make an end run around the Weldon Amendment on the back of § 46.202(f), while ignoring the effect of the objected-to drugs and devices on human embryos existing at least five to six days prior to implantation.

In addition to prohibiting the fines Petitioners seek to impose on Respondent, the Weldon Amendment also establishes that religious objections to abortion are legitimate and worthy of accommodation. Section 46.202(f) does not ameliorate the Respondents' conscientious objections to providing drugs and devices that can terminate the existence of a human embryo. The Code of Federal Regulations is hardly an answer to Respondents' religious objections, and it cannot justify the substantial burdens imposed by the Petitioners on Respondents.

CONCLUSION

A mere regulatory definition cannot overcome the biological fact that a human embryo is created by fertilization *five to six days* before implantation of that embryo in the endometrium. Drugs and devices that prevent implantation destroy that human embryo and terminate the pregnancy. Indeed, under normal usage as reflected in dictionaries, killing an embryo and terminating a pregnancy is an abortion.

Respondents cannot define away this reality, given that even the Code of Federal Regulations in most cases understands or even defines pregnancy based upon the existence of an embryo—without regard to whether that embryo has implanted. Petitioners' requirement that Respondents provide coverage for abortifacient drugs and devices is a substantial burden on religious opposition to abortion and a violation of the Weldon Amendment. This Court should affirm the opinion issued in this case by the en banc United States Court of Appeals for the Tenth Circuit.

Respectfully submitted,

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