#### **EDITOR'S NOTE**

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## Early Pregnancy Complications

## and the Ethical and Religious Directives

By RON HAMEL, PhD

he last few months of 2013 and the very beginning of 2014 saw several attacks on Catholic health care, more specifically, on how Catholic health care addresses obstetrical complications. These were not the first such attacks. However, the particularly sensational American Civil Liberties Union lawsuit against the United States Conference of Catholic Bishops (USCCB), which claims that the *Ethical and Religious Directives for Catholic Health Care Services* issued by the USCCB were responsible for "negligent care" of a pregnant woman with an obstetric emergency being treated in a Michigan Catholic hospital, calls for a careful discussion of the understanding and application of the *Directives*.

Though tragic events have been attributed to precise observance of the *Directives*, situations such as the Michigan case rarely are the result of applying the *Directives* as they were written. In some instances, there may have been a lack of knowledge about what specific directives actually say, or a misunderstanding or misapplication. But that is more a matter of interpretation than intention.

In the hope of clarifying the guidance provided by the *Directives* and Catholic moral tradition, let's examine four areas relating to obstetric complications: informed consent, ectopic pregnancy, miscarriage and preterm premature rupture of membranes (PPROM). These are the primary issues that repeatedly are at the heart of how Catholic health care deals with obstetric complications.

#### **CONVICTIONS AND PRINCIPLES**

Several fundamental beliefs and ethical principles shape the Catholic approach. First is respect for the dignity of all human beings. This entails seeking the well-being and flourishing of all, including nascent human life, and doing nothing that would violate the inherent value of any human life, whether of the mother or the fetus.

In this regard, the *Directives* state, "The Church's commitment to human dignity inspires an abiding concern for the sanctity of human life from its very beginning," and "Catholic health ministry witnesses to the sanctity of life 'from the moment of conception until death.' The Church's defense of life encompasses the unborn and the care of women and their children during and after pregnancy."

As an immediate consequence of this fundamental conviction, Catholic hospitals will attempt to save both lives in cases of obstetrical complications. For the vast majority of cases, this is exactly what the mother or parents want. They want to try to save the pregnancy, to have this child, and they want to do whatever is feasible

to try to make that happen. Respecting human dignity in these cases means seeking the well-being of both mother and fetus to the degree that it is possible.

A second consequence of this grounding belief is the moral principle that prohibits the directly intended ending of a pregnancy before viability, or the directly intended destruction of a viable fetus. Either would constitute a direct abortion. Directive 45 addresses this. But it is not the last word

Some procedures do not directly intend the termination of a pregnancy and do not have ending a pregnancy as their sole, immediate effect. Such procedures are considered to be indirect abortions and can be morally permissible. They are justified on the basis of the principle of double effect, another of the ethical principles that shape how obstetric complications are handled in a Catholic facility.

The principle of double effect applies when

an action has at least two simultaneous effects — one good and intended, the other bad and foreseen but not intended. The principle has four conditions, all of which must be present for an action to be considered "indirect," thus morally acceptable.

- The act in question (or the procedure) must be "good" or "neutral" in its moral quality
- The good effect is intended, not the bad
- The good and bad effects must occur simultaneously, thus avoid-

ing a situation in which the bad effect becomes a means for achieving the good effect. Morally speaking, in the Catholic tradition and elsewhere, one ought not use a bad means to achieve a good end.

■ There should be a proportionate reason, that is, a sufficiently serious reason, to permit the bad effect

This principle of double effect gives rise to several directives that provide guidance when dealing with particular obstetrical complications. First, however, we turn to an issue that is not an obstetrical complication, but is foundational to all decision-making — informed consent.

#### INFORMED CONSENT

One of the charges made in the Michigan case is that the patient involved was not adequately informed about her condition and her choices. This failure is laid at the feet of the *Directives*.

Directive 26, however, states, "The free and informed consent of the person or the person's surrogate is required for medical treatments and procedures ...." Directive 27 is somewhat more specific. It reads: "Free and informed consent requires that the person or the person's surrogate receive all reasonable information about the essential nature of the proposed treatment and its benefits; its risks, side-effects, consequences, and cost; and any reasonable and morally legitimate alternatives, including no treatment at all." Directive 28 further states, "Each person or the

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person's surrogate should have access to medical and moral information and counseling so as to be able to form his or her conscience. The free and informed health care decision of the person or the person's surrogate is to be followed so long as it does not contradict Catholic principles."<sup>2</sup>

It is important to keep in mind the distinction between a direct termination of pregnancy, which is morally prohibited, and an indirect termination of pregnancy, which is morally permissible when there is a sufficient reason. Quite probably, indirect abortions would cover the vast majority of

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early pregnancy complications in which a termination of pregnancy seems to be medically indicated to resolve the complication. There should be no question about informing a woman of the possibility of a termination of her pregnancy that is indirect in those situations in which it is medically indicated or is a medically feasible option.

However, what about a direct abortion? Can that be mentioned as part of the informed consent process? While some will disagree, the full

disclosure of medically appropriate or indicated options, factually relevant information — including direct abortion — in difficult obstetrical situations can and should occur, within certain parameters.

It is no mistake that Directives 26-28 come under Part Three of the *Directives*, a section that reflects on the nature of the patient-professional relationship. The individual directives within Part Three discuss critical features of this relationship and outline some of the basic rights and respon-

sibilities of patients and professionals alike. It is also no mistake that the Introduction to Part Three, as well as Directive 23, reaffirm the notion of respect for human dignity, which is seen as the foundation of the professional-patient relationship. Informed consent is an expression of respect for human dignity. To violate informed consent is to violate human dignity. Intimately related to human dignity and to informed consent is conscience, as underscored in Directive 28.

Human beings ought to make decisions that are true to their consciences, to what they discern, in their heart of hearts, that God is calling them to be and do in the concrete. This is a difficult task, made all the more difficult when people are not given complete information by those they trust to provide it.

A basic moral responsibility of providers in Catholic health care organizations is to communicate factually relevant information to patients so they can properly inform their consciences. Directive 28 describes this well: "Each person or the person's surrogate should have access to medical and moral information and counseling so as to be able to form his or her conscience." Receiving such factually relevant information, of course, is only one piece in the formation of an individual's conscience. Much more is required.

Directive 28 is important for several reasons. First, it recognizes the primacy of conscience by stating that the patient should be given medical and moral information necessary to inform her or his conscience. In so doing, the directive suggests that providers in Catholic health care facilities cannot usurp the moral authority of a patient to direct her or his own life according to her or his conscience by failing to disclose factually relevant information.

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Second, the directive implicitly makes a crucial moral distinction between disclosing information and providing services that are not in keeping with church teaching. It does this by indicating that providers in Catholic health care facilities need not honor all patient decisions, especially those that violate Catholic principles, but they must share factually relevant information with a patient so that she or he can inform her or his conscience. This moral distinction is indispensable if providers in Catholic health care facilities are going to fulfill their medical, moral and legal responsibilities to patients, while at the same time preserve their identity and professional integrity in a morally pluralistic society, as well as the faithbased identity of the organization.

Third, Directive 28 speaks to moral information. This is another essential component of the formation of conscience and ought not to be overlooked in the clinical context. In fact, disclosure of factually relevant information is an opportunity for providing the patient with moral considerations.

It is in the Introduction to Part Three that we find another compelling reason, beyond that of informing conscience, why providers in Catholic hospitals have a moral responsibility to disclose fully all factually relevant information to the

patient. In a word, that reason is trust. Among the building blocks of the patient-professional relationship, trust is essential if the patient is going to feel free to share personal information necessary for effective care, as well as heed the expert advice of the professional when it comes to following the care plan.

If physicians in Catholic hospitals were to routinely and systematically refrain from disclosing factually relevant information, to what extent would that weaken the trust patients have in them and the health care professionals that practice in Catholic facilities? This is not a rhetorical question. It is one that must be taken seriously. The ability of physicians to carry out their healing mission would be gravely undermined if the building block of trust were weakened or destroyed altogether. Of course, there are other reasons for full disclosure of factually relevant information legal requirements associated with informed consent, avoidance of malpractice lawsuits and, above all, avoidance of serious harm to the pregnant woman.

While there are important moral reasons for providing patients with all factually relevant information, the way in which the information is imparted is a critical component of the disclosure process. When it comes to actually stating the prohibited option, providers in Catholic health care organizations should do so in an objective, factual manner, neither approving nor recommending, pointing out that the procedure is not offered in the Catholic facility and explaining why this is the case.

This is critical for full disclosure to be acceptable morally. It is critical for the patient's own moral education and the formation of his or her conscience, as well as for the integrity of the institution and the professional integrity of the provider. A number of Catholic health care facilities with obstetric departments, especially those that deal with high acuity patients, have a template or script to assist physicians and other clinicians in this communication.

#### **ECTOPIC PREGNANCY**

In an ectopic pregnancy, an embryo attaches to something other than the endometrium, usually the wall of the fallopian tube. The resulting abnormal growth can result in rupture of the tube, severe hemorrhaging and even death for the mother. In developed countries, the death rate from ectopic pregnancies is approximately 9 percent to 13 percent, while in undeveloped countries, it is considerably higher.

Treatment of ectopic pregnancy can take three forms:

- Expectant management consists of simply monitoring the situation to see if the tubal pregnancy resolves on its own. Most women are not candidates for expectant management.
- Surgical treatment can take two forms. One is salpingectomy, the partial or complete removal of the fallopian tube that also contains an embryo. The other is salpingostomy, slitting the fallopian tube and "stopping the destructive activity of the trophoblast by removing the invasive trophoblastic cells along with the damaged tubal tissue." The embryo is also necessarily removed in the process.
- Medical treatment consists of administering the drug methotrexate. It prevents the trophoblastic cells from continuing to divide and do damage to the fallopian tube that could result in severe hemorrhaging. The embryo also eventually dies.

For ectopic pregnancies, the use of methotrexate seems increasingly to be the preferred treatment because it does not involve surgery and it leaves the woman's fertility intact. Salpingostomy can also preserve the woman's fertility.

Directive 48 specifies, "in case of extrauterine pregnancy, no intervention is morally licit which constitutes a direct abortion." In light of Directive 48, the question is whether any of the procedures mentioned above constitutes a direct abortion. While salpingectomy results in the death of the embryo, the embryo's demise is not intended, nor is there any direct attack on the embryo. A pathological tube is removed that results in two effects — prevention of harm to the mother (the intended effect) and the demise of the embryo (the unintended effect). There is clearly a proportionate reason — the mother's well-being is preserved, and the embryo, though it dies, actually has no chance at survival. Virtually all theologians agree that salpingectomy constitutes an indirect abortion and so is morally licit. The demise of the embryo is foreseen, but not intended.

Among Catholic theologians and ethicists, there is disagreement regarding salpingostomy and administering methotrexate. Some see them as a direct attack on the embryo and, so, a direct

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abortion,4 while others see them as aimed at removing pathological tissue — the trophoblast - which unavoidably results in the death of the embryo. They judge this to be an indirect abortion.5 For example, bioethicist Rev. Albert Moraczewski, OP, PhD, referring to salpingostomy, says: "One can consider this an indirect abortion. This conclusion ... is based on stopping the destructive activity of the trophoblast by removing the invasive trophoblastic cells along with the damaged tubal tissue."6 With regard to the use of methotrexate, he says: "Analysis on the use of methotrexate (MTX) ... proceeds along a similar line of reasoning except that the action is biochemical rather than surgical."7 Moral theologians Rev. Benedict Ashley, OP, PhD, Sr. Jean deBlois, CSJ, PhD, and Rev. Kevin O'Rourke, OP, JCD, similarly explain the use of methotrexate: "[M]ethotrexate is often used to treat the pathology caused by the abnormal location of the fertilized ovum. While it would be wrong to detach a fertilized ovum from its normal site of implantation, to detach it from an abnormal site that constitutes a serious pathological condition in the woman's body would seem to be licit. Hence, the direct intrinsic intention ... of the surgical or pharmaceutical act ... seems to be to protect the health of the mother, and the death of the conceptus is not intended. For this reason, it is our opinion that salpingostomy and the use of methotrexate do not result in direct abortion and therefore are in accord with Directive 48."

The magisterium has not resolved this controversy. Hence, neither church teaching nor the *Directives* forbid the third or fourth approaches (so long as these approaches can legitimately be argued as not constituting direct abortions). Currently, both opinions are in play.

If some Catholic hospitals have policies that prohibit salpingostomy and the use of methotrexate, this is not because these procedures are forbidden by church teaching or by the *Directives*. Rather, it is because an individual — or individuals — decided either to take the safer course or personally believed that salpingostomy and the use of methotrexate constitute direct abortions and are, therefore, in conflict with Directives 48 and 45.

However, given the ongoing debate, it is permissible for Catholic hospitals to employ both salpingostomy and methotrexate. As the editors of the National Catholic Bioethics Center's Catholic Health Care Ethics: A Manual for Practitioners

note: "Resolution of the debate will depend on further specification of the exact nature of these medical procedures and further refinement of the arguments about the moral object of each act. Generally, if there are two competing but contrary bodies of theological opinion about a moral issue, each held by experts whose work is in accordance with the magisterium of the Church, and if there is no specific magisterial teaching on the issue that would resolve the matter, then the decision makers may licitly act on either opinion until such time that the magisterium has resolved the question."

#### **MISCARRIAGE**

Another of the obstetric complications that the *Directives* supposedly prevent from being adequately treated is miscarriage, of which there are several types. A missed miscarriage occurs when there is a fetal demise, but there is no uterine activity to expel the products of conception. A complete miscarriage occurs when all the products of conception have been expelled without the need for surgical or medical intervention. A threatened miscarriage occurs when any bleeding is seen during pregnancy prior to 20 weeks' gestation. Upon examination, it may be found that the fetus remains viable and the pregnancy continues without any further problems. Expectant management (i.e., bed rest) is the typical treatment.

When there is vaginal bleeding with dilation of the cervix, however, and the fetus has not yet been expelled, an inevitable miscarriage exists. In these cases, bleeding can be severe, and abdominal pain and cramping often occur. This situation virtually always progresses to a complete miscarriage. There may or may not be a fetal heartbeat.

An incomplete miscarriage occurs when there has been expulsion of some, but not all, of the products of conception before the 20th week of pregnancy. Parts of the fetus, placenta or membranes might have been retained. Vaginal bleeding is heavier, and abdominal pain is almost always present. The mouth of the womb is open, and the pregnancy tissue is being expelled.

Some miscarriages can become septic. In a septic miscarriage, tissue from a missed or incomplete miscarriage becomes infected, and there is a risk the infection will spread (septicemia), posing a grave risk to the life of the mother.<sup>10</sup>

There are three treatment options for miscarriage — expectant management or watchful wait-

ing, surgical evacuation of the products of conception and medical (chemical) evacuation.

With expectant management or watchful waiting, 65 percent to 80 percent of miscarriages resolve within two to six weeks with no higher a complication rate than from a surgical intervention. Nor is there any difference in short-term psychological outcomes.

Surgical treatment (dilation and curettage or vacuum aspiration) is the fastest way to complete the miscarriage. It shortens the duration and heaviness of bleeding and avoids the pain associated with miscarriage, but it has its own complications. Medically, surgical treatment is indicated when the woman has unstable vital signs, uncontrolled bleeding or evidence of infec-

troiled bleeding or evidence of infection. Some studies suggest that there is no indication for routine surgical management. Selection of treatment obviously depends on the clinical situation and the patient's judgment.

While surgical intervention has been the conventional treatment for first-trimester pregnancy loss and is the treatment of choice for patients whose condition is unstable, nonsurgical treatments increasingly have been introduced and appear to be effective and satis-

Medical management involves the use of a drug, generally misoprostol, to prompt the completion of the miscarriage. It has been shown to be as effective as manual vacuum aspiration, with complete evacuation rates of 95 percent to 99 percent after one or two weeks.

#### **ETHICAL CONSIDERATIONS**

factory for certain patients.11

Regarding these treatments, it is critical to note that ethical considerations cannot be raised in a vacuum. They must always be taken into account in conjunction with the clinical situation, especially the medical and psychosocial condition of the mother, and what is possible clinically. Two directives are relevant here. Directive 45 states: "Abortion (that is, the directly intended termination of pregnancy before viability or the directly intended destruction of a viable fetus) is never permitted. Every procedure whose sole immediate effect is the termination of pregnancy before viability is an abortion...."

And, the second, Directive 47, states: "Operations, treatments, and medications that have as

their direct purpose the cure of a proportionately serious pathological condition of a pregnant woman are permitted when they cannot be safely postponed until the unborn child is viable, even if they will result in the death of the unborn child."

Several things need to be noted and kept in mind regarding Directive 47: The direct purpose of the intervention is to save the life of the mother or protect her health, and not to terminate the life of the fetus. Second, the woman must have a proportionately serious pathological condition, and the intervention is a treatment or cure for that. Third, the intervention should be a last resort (i.e., waiting is not feasible, and lesser means have not

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been or will not be effective). Fourth, the directive recognizes that the intervention might result in the death of the fetus, hence, in some cases, the presence of fetal heart tones does not preclude an intervention.<sup>12</sup>

In light of the guidance provided by these directives, which of the treatment options would seem to be morally acceptable for the various types of miscarriage? Obviously, in cases of a complete miscarriage, there is no question of treatment. In a threatened miscarriage, expectant management is the morally acceptable treatment because the fetus remains alive and the pregnancy may continue on to term. This is most likely the preferable option for most women, because they want their pregnancy and will do what is necessary to give it every chance of coming to term. Medical (chemical) and surgical treatment would not seem to meet the requirements of Directive 47 or the conditions necessary for an indirect abortion.

When an inevitable miscarriage is at issue, expectant management and medical therapy would both be morally acceptable. If expectant management is not feasible due to excessive bleeding and pain or other factors such as the

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clinical ability of the facility, the use of a pharmaceutical agent to induce labor is not a direct attack on the fetus, but rather a measure to evacuate the uterus in order to resolve a pathological condition. Evacuation of the uterus is the only way to ultimately resolve the pathological condition, in the situation of an inevitable miscarriage. The use of a chemical agent to induce labor is simply

helping to complete what already has begun naturally and which needs to be completed. This would be considered an indirect abortion, from a Catholic perspective.

Surgical management in this situation is more ambiguous. On the one hand, it would seem to be a direct attack on the fetus. On the other hand, surgical management is aimed at evacuating

all the products of conception from the uterus, of which the fetus is one. In this sense, could it be considered indirect?

In the case of an incomplete miscarriage, because the fetus is already dead, any of the forms of treatment would be morally permissible. The primary concern here should be the well-being of the mother. The same would be true of a septic miscarriage. Whenever the fetus is already deceased, the method of evacuation of the uterus can be determined solely on medical considerations and the judgment of the mother.

#### **PPROM**

Preterm premature rupture of membranes, that is, either the complete breakage of the amniotic sac or leakage of amniotic fluid before 37 weeks of gestation (i.e., before labor and before the fetus has reached maturity), occurs in about 2 percent to 3 percent of all pregnancies. The condition poses a potentially grave risk to the fetus, which is likely to be delivered within one week of membrane rupture and faces complications of prematurity and even death (preterm delivery). PPROM also poses a serious risk of chorioamnionitis — an infection of placental tissues which can lead to the death of both the mother and fetus within a very short time.

Bioethicist Peter J. Cataldo, PhD, and T. Murphy Goodwin, MD, professor of obstetrics and gynecology at the University of Southern California, observe, "The main risk to mother and fetus in PPROM is the development of infection within the uterus, since the amniotic sac no longer serves as a barrier against infection. The burden on the mother and the fetus is the risk of infection, but

depending on how early in pregnancy the rupture occurs, the risk of prematurity may be more significant for the fetus."<sup>13</sup>

Treatment for PPROM includes hospitalization, expectant management, monitoring for signs of infection, administration of antibiotics and possibly tocolytics to stop pre-term labor, and induction of labor to resolve chorioamnionitis should

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that occur. Determination of appropriate treatment depends to a considerable degree on when PPROM occurs in the pregnancy (the earlier in the pregnancy, the less chance there is for fetal survival and the higher incidence there tends to be for infection), and the clinical condition of the mother, as well as her socioeconomic reality.

Later in the early part of the pregnancy, conservative management may reduce the risks of prematurity for the fetus, keeping in mind that the vast majority of women proceed to active labor and delivery soon after PPROM. Few remain pregnant more than three or four weeks after.

Ethically, if infection develops, Directive 47 provides guidance. Labor and delivery may be induced. This would constitute an indirect abortion because it fulfills the conditions of the principle of double effect. As explained by Cataldo and Goodwin, "If evidence of intrauterine infection develops, however, progressive, severe infection of the mother and the fetus can be expected within hours, a life-threatening situation for both. In this setting, induction of labor for maternal benefit is commonly recommended in practice, even though the fetus cannot be expected to survive." <sup>14</sup>

They also address whether, in PPROM cases, induction of labor before 23 weeks' gestation ever can be ethically justified. After noting that in Catholic moral teaching and tradition, induction of labor is evaluated by the principle of double effect, they explain: "In the case of PPROM with evidence of infection in the uterus, the intention of the physician inducing labor is to cure the infection by removing the infected placenta and membranes of the gestational sac. The good effects of curing the mother of ... PPROM are not caused by

the death of the baby [third condition]. ... [T]he removal of the offending organ, the placenta and membranes, allows survival of the mother, which would otherwise be in doubt [fourth condition]." Finally, they go on to say that there is ample published evidence that when there is no clinical or laboratory evidence of infection, "expectant management and use of antibiotics is an acceptable course that can result in fetal survival and acceptable maternal morbidity." If

#### IMPORTANCE OF CLINICAL DATA

Sr. deBlois and Fr. O'Rourke, in discussing Part Four of the Directives, offer the following advice in understanding and applying these directives, especially those discussed here: "[A]ppropriate interpretation and application of the Directives also require adequate medical data and an understanding of the pathophysiology of the conditions involved. ... For example, in seeking to observe the norms set forth in Directives 47, 48 and 53, one must know the physical condition of the person in question. It is important to note here that Directive 47 (treating a serious pathological condition of a pregnant woman) and 48 (treating an extrauterine pregnancy) do not seek to impose conclusions divorced from clinical data. Rather, they set parameters within which clinical data must be presented, analyzed, and acted on."17

In making decisions about a course of action in these crisis situations, there are multiple variables to consider, including the medical condition of the mother, the age of gestation of the fetus, accepted standards of care for dealing with these situations, the level of clinical care that is available, the patient's living and family situation and the woman's physical, emotional and psychological capacities, among others. These decisions are so often highly complex and too often very tragic. Of utmost importance is doing what can be done for the well-being of both the fetus and the mother. The guidance provided by the Directives should assist in that discernment, recognizing that some situations lie in the gray zone and some decisions will not be perfect.

While some decisions about how to address complications early in a pregnancy are relatively straightforward, others are highly complex, both medically and ethically. There can be numerous variables at play: rapidly changing situations; a need for relatively quick decisions; and the fact that Catholic health care is committed to the wellbeing of both the mother and the fetus, whose

interests sometimes conflict.18

Given this reality, the wisdom of Sr. deBlois and Fr. O'Rourke should be taken to heart by those who have a responsibility for assisting in these decisions. In their book, the authors conclude their discussion of Part Four of the *Directives* with the following advice: "Appropriate ... respect for unborn human life requires much more than mere adherence to the prescriptions and proscriptions expressed in Part Four. Although specific directives set the parameters for determining appropriate action on behalf of human good, they do not exempt decision makers from reasoned analysis and conscientious decision making."

They go on to say: "The nature of the materials addressed in Part Four should lead ethics committees [and, I might add, others who provide ethical guidance] in Catholic health care to educate themselves and ensure they understand the issues. Moreover, ethics committees should carry out ongoing educational activities to promote better understanding of the issues and help shape organizational policy and practice in ways that promote the goods and values in question."

There is too much at stake in these situations and in these decisions to be unprepared.

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#### NOTES

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2. Ethical and Religious Directives, Part Four, directives 26, 27, 28.

3. Albert S. Moraczewski, "Ectopic Pregnancy: B. Arguments in Favor of Salpingostomy and Methotrexate," in Edward J. Furton et al., eds., *Catholic Health Care Ethics: A Manual for Practitioners* (Philadelphia: The National Catholic Bioethics Center, 2009), 122.

4. See, for example, William E. May, "Ectopic Pregnancy: A. Arguments against Salpingostomy and Methotrexate," in *Catholic Health Care Ethics: A Manual for Practitioners*, 119-22, and Edward J. Furton, "The Direct Killing of the Innocent," *Ethics & Medics* 35, no. 10 (October 2010): 1-2.

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- 17. DeBlois and O'Rourke, 28.
- 18. Cataldo and Goodwin, 111.
- 19. DeBlois and O'Rourke, 31.

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