Washington Insider

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As this was written in early July 2014, by far the most important bioethics-related news in Washington was the US Supreme Court's decision in cases brought against the US Department of Health and Human Services contraception mandate by Hobby Lobby and Conestoga Wood Industries. As noted in earlier columns of this series, if federal courts determine that faith-based organizations may not exercise their religious freedom by opting out of government mandates regarding drugs and devices that can attack the early human embryo, it is unlikely that those organizations will have a right to follow their convictions on other bioethics issues.

Other developments in Washington, DC, included a new legislative proposal to restrict religious groups' freedom by statute, and discussion at the Food and Drug Administration about the "three-parent embryo."

Hobby Lobby and *Conestoga*: A Victory for Religious Freedom

On June 30, 2014, at the end of its October 2013 term, the US Supreme Court handed down its long-awaited decision in the *Hobby Lobby* religious freedom case. At issue was the right of three family-owned companies to exclude from their employer health plans four specific drugs and devices to which they have a religious objection because of potential abortifacient effects.[1] The companies had filed suit because HHS, led by Kathleen Sebelius and then by Sylvia Burwell, was implementing a nationwide

[1] See *Burwell v. Hobby Lobby Stores, Inc.*, nos. 13–354 and 13–356, slip op. (U. S. June 30, 2014). The decision on Hobby Lobby Stores, owned by the Green family, also applies to Mardel Inc., a chain of Christian bookstores operated by a member of this family. Combined with this case for purposes of a decision was *Conestoga Wood Specialties Corp. v. Burwell*, in which the Hahn family sought similar relief. Hobby Lobby had prevailed in its suit before the Tenth Circuit Court of Appeals, while Conestoga had been denied relief by the Third Circuit.

contraception mandate demanding that virtually all health plans cover such drugs and devices as part of the Affordable Care Act's "preventive services" mandate.

The Court's 5-to-4 decision in favor of the religious freedom of these family-owned companies was immediately greeted by a hailstorm of negative, misleading, and ignorant commentary by those who are politically committed to mandatory contraceptive coverage for all Americans. However, what the court did, in fact, was follow its own precedents and faithfully apply a law passed almost unanimously by the people's elected representatives.

That law is the Religious Freedom Restoration Act (RFRA), which was approved by the 103rd Congress almost unanimously in 1993 and signed into law by President Bill Clinton. RFRA says that a federal policy cannot "substantially burden" a person's religious freedom unless it furthers a "compelling governmental interest" in the way that is "least restrictive" of that freedom.

The Court's majority opinion by Justice Samuel Alito concluded that, even if one assumes that the government has a "compelling" interest in maximizing birth control coverage, it had failed to show that it was furthering that interest by the means that is least restrictive of religious freedom. Among other things, the government could provide that coverage itself, as it already does to millions of Americans through programs like Medicaid and the Title X family planning program. In fact, the Obama administration had already offered an "accommodation" to nonprofit religious employers that, whatever else may be said about it, would be "less restrictive" of Hobby Lobby's religious freedom than the mandate it was being held to obey. (This "accommodation" will be the subject of further comment below.) So the current regulation governing companies like Hobby Lobby had to fall.[2]

In reaching this conclusion, of course, the Court also had to decide, Can a for-profit family-owned business have religious freedom rights? It noted the following: Courts treat corporations as "persons" in various ways, they treat nonprofit corporations as having religious freedom, and they have said that people do not lose their religious freedom just because they run a business. The majority noted that many corporations serve altruistic or charitable aims in addition to making a profit, and it could find no persuasive argument why those aims cannot include religious objectives like those stated by the Green and Hahn families. So the logical answer to the question is yes.[3]

The majority opinion also explained how limited this decision is. It concerns only "closely held" corporations like family-owned businesses, leaving to a future date any discussion of publicly traded corporations whose religious views, if any, could be difficult to determine. The decision is restricted to the HHS contraceptive mandate, so it does not provide any new instrument for contesting, for example, laws forbidding discrimination based on race or laws requiring Americans to pay taxes.[4]

[2] *Burwell v. Hobby Lobby*, slip op. at 40–45.

[3] Ibid. at 19–25.

[4] Ibid. at 45–49.

These explanations did not prevent fierce criticism by four members of the Court and by various politicians and pundits. The chief dissent, by Justice Ruth Bader Ginsburg joined by Justice Sonia Sotomayor and on most points by Justices Stephen Breyer and Elena Kagan, simply got the facts wrong in important ways. For example, Justice Ginsburg said the exemption sought by Hobby Lobby "would deny legions of women who do not hold their employers' beliefs access to contraceptive coverage."[5] Yet as the majority explained, and as Justice Anthony Kennedy emphasized in his additional concurring opinion, the "accommodation" offered to nonprofit religious groups would shift the burden of providing the very same objectionable coverage from the employer to its insurance company—with the result that the effect on coverage for Hobby Lobby's female employees would be "precisely zero."[6]

Another fallacy in the Ginsburg dissent is found in its attempt to distinguish nonprofit religious organizations from for-profit companies: "Religious organizations exist to foster the interests of persons subscribing to the same religious faith. Not so of for-profit corporations. Workers who sustain the operations of those corporations commonly are not drawn from one religious community."[7] This is simply and demonstrably false. Catholic nonprofit hospitals and schools, for example, exist to serve the interests of anyone in need; they both employ and serve people of other faiths and no faith.

The Ginsburg dissent also states, "Any decision to use contraceptives made by a woman covered under Hobby Lobby's or Conestoga's plan will not be propelled by the Government, it will be the woman's autonomous choice, informed by the physician she consults."[8] But surely this is irrelevant to the case at hand, where the companies are not claiming any right to be involved in a woman's choice to *use* contraceptives (or abortifacients). Quite the opposite: they wish to be left out of that transaction altogether. Their objection is to providing and paying for the *coverage* that promotes some of these items. And regarding the coverage, the government's mandate is as coercive for female employees as it is for employers—neither has any right to opt out. In this connection, it is amazing how many pundits and politicians simply assume that Christian-owned companies have *no* employees who share their values or would concur in their religious objections to contraceptives or abortifacients.

But false assumptions are now standard practice for those wishing to vilify anyone who disagrees with their preconceived political beliefs. "The immediate effect" of the Court's decision, intoned *The New York Times*, "was to deny many thousands of women contraceptive coverage vital to their well-being and reproductive freedom."[9] We must "keep bosses out of the examination room," said Senate

[5] *Burwell v. Hobby Lobby*, slip op. at 8 (Ginsburg, J., dissenting).

[6] *Burwell v. Hobby Lobby*, slip op. at 4; slip op. at 3 (Kennedy, J., concurring).

[7] *Burwell v. Hobby Lobby*, slip op. at 16 (Ginsburg, J., dissenting).

[8] Ibid. at 23.

[9] "Limiting Rights: Imposing Religion on Workers," editorial, *New York Times*, June 30, 2014, http://www.nytimes.com/2014/07/01/opinion/the-supreme-court-imposing-religion-on-workers.html.

Majority Leader Harry Reid.[10] Talk show host Rachel Maddow said that employees' beliefs have been "effectively overruled by the religious beliefs of the boss"—ignoring the fact that employees retain complete freedom to make any decision they wish on contraception, and under the "accommodation" mentioned by the Court would also continue to receive "free" coverage for all methods.[11]

The Court's discussion of the "accommodation" offered to many nonprofit religious organizations deserves further comment. The HHS mandate allows a genuine religious exemption almost exclusively for houses of worship. For the great majority of nonprofit religious organizations—hospitals, schools, universities, and charitable institutions—it offers only an "accommodation" designed to ensure that all the organization's employees still receive full coverage for contraceptive and abortifacient drugs and devices. However, Little Sisters of the Poor and other nonprofit Catholic organizations now pursuing their own cases to the Supreme Court object to this "accommodation" as well.

It is easy to see why, once one understands how the "accommodation" works. Take the case of a self-insured Catholic organization. As a matter of federal law, the third-party administrator who handles claims under the organization's health plan can administer the plan only in the way that the organization has instructed it to, through the "instrument" establishing the plan. Now the federal government tells the organization it must provide health coverage that violates its religion, or at least submit a formal certification to its third-party administrator stating its objection to this coverage. Under the HHS regulations, signing this certification gives the administrator the legal authority to provide the very coverage to which the organization objects. In other words, when the religious organization tries to say "no" to certain items it deems morally unacceptable, it will really be saying "yes." But as the Little Sisters of the Poor and others have said: Just as they cannot sin, "they cannot deputize a third party to sin on their behalf."[12]

Now that the Supreme Court majority has apparently cited the "accommodation" as an option that *may* be acceptable to both the government and Hobby Lobby, with Justice Kennedy especially emphasizing this approach, does this undermine the Little Sisters' case? Some commentators have thought so, even to the extent of asking, "To get Kennedy on board, did Alito throw Little Sisters under the bus?"[13]

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[10] Office of Sen. Harry Reid, "Reid Statement on Supreme Court Decision Denying Women the Right to Make Their Own Health Care Decisions," news release, June 30, 2014, http://www.reid.senate.gov/press_releases/2014–30–06-reid-statement-on-supreme-court-decision-denying-women-the-right-to-make-their-own-health-care-decisions#.U7nlIKjD-P8.

[11] See Katherine Fung, "Rachel Maddow Explains Why the Supreme Court's Hobby Lobby Ruling Is Such A Major Blow," *Huffington Post*, July 1, 2014, http://www.huffingtonpost.com/2014/07/01/rachel-maddow-hobby-lobby-scotus_n_5547211.html.

[12] See Robert Pear, "Justices Are Asked to Reject Nuns' Challenge to Health Law," *New York Times*, January 3, 2014, http://www.nytimes.com/2014/01/04/us/politics/obama-administration-urges-court-to-reject-nuns-health-law-challenge.html.

[13] M. Peppard, "To Get Kennedy on Board, Did Alito Throw Little Sisters under the Bus?," *Commonweal* blog, July 1, 2014, https://www.commonwealmagazine.org/blog/get-kennedy-board-did-alito-throw-little-sisters-under-bus.

In other words, is the Court saying as a matter of principle that the "accommodation" is sufficient to address religious groups' concerns under the Religious Freedom Restoration Act, prejudicing claims such as those put forward by the Little Sisters?

There are at least three features of the Court's opinion that cast doubt on this conclusion.

First, the accommodation comes into play in the majority opinion only for purposes of determining that, with respect to these plaintiffs, a means less restrictive of religious freedom existed for advancing the government's interests. Thus, the mandate actually imposed on these plaintiffs could not be the "least restrictive" means available to the government, as required under RFRA. The government itself had said in effect that it saw the accommodation as less restrictive, by offering it to religious nonprofits. As for the three companies themselves, they took no position on whether the accommodation would satisfy their religious objections, because it had not been offered to them.[14] So that question was not before the court.

Second, setting aside the unanswered question whether the accommodation could be acceptable to these three companies, the majority opinion says explicitly that it is not deciding the issue of whether it could be acceptable to others. Justice Alito writes, "We do not decide today whether an approach of this type [i.e., the accommodation that HHS offered to religious nonprofits] complies with RFRA for purposes of all religious claims."[15] This disclaimer did not escape the notice (and criticism) of the dissent.[16]

Third, the majority in *Hobby Lobby* insisted that courts may judge (as they traditionally have for purposes of deciding religious liberty claims) whether an organization's religious objection is sincere, but they have no business judging whether its objection is correct or reasonable. Responding to the dissent's argument that these companies are not substantially burdened because they are not directly involved in the decision to use contraception, the majority (including Justice Kennedy) said,

> The Hahns and Greens believe that providing the coverage demanded by the HHS regulations is connected to the destruction of an embryo in a way that is sufficient to make it immoral for them to provide the coverage. This belief implicates a difficult and important question of religion and moral philosophy, namely, the circumstances under which it is wrong for a person to perform an act that is innocent in itself but that has the effect of enabling or facilitating the commission of an immoral act by another. Arrogating the authority to provide a binding national answer to this religious and philosophical question, HHS and the principal dissent in effect tell the plaintiffs that their beliefs are flawed. For good reason, we have repeatedly refused to take such a step.[17]

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[14] "We haven't been offered that accommodation," counsel for the companies explained during oral argument, "so we haven't had to decide what kind of objection, if any, we would make to that." Transcript of oral arguments, March 25, 2014, 86–87, quoted in *Burwell v. Hobby Lobby*, slip op. at 30 (Ginsburg, J., dissenting).

[15] *Burwell v. Hobby Lobby*, slip op. at 44.

[16] *Burwell v. Hobby Lobby*, slip op. at 29–30 (Ginsburg, J., dissenting).

[17] *Burwell v. Hobby Lobby*, slip op. at at 36–37.

So even if a particular organization (whether for-profit or not) believed that the "accommodation" distanced it sufficiently from immoral activity to satisfy its own religious objections, that would not foreclose a different judgment on the part of the Little Sisters of the Poor or others who have different theological convictions about complicity in immoral actions. To conclude otherwise would be to assume "the authority to provide a binding national answer to this religious and philosophical question," precisely what the majority says courts may not do.

In fact, the Supreme Court has already issued orders in two cases involving religious nonprofits. A unanimous court granted temporary injunctive relief to the Little Sisters of the Poor on January 24.[18] In the more contentious climate following the *Hobby Lobby* decision, six justices agreed to give similar relief to Wheaton College while its case is pending.[19] The nonprofits were told they must notify the federal government of their objection, but need not complete the administration's self-certification form or transmit it to their insurance issuer or third-party administrator. The Court made it clear that these are not final decisions on the merits of these cases. Yet Justice Sotomayor, joined by Justices Ginsburg and Kagan, filed an indignant dissent against the order in the *Wheaton College* case, insisting that it contradicts what she sees as the Court's statement in *Hobby Lobby* that the "accommodation" fulfills the requirements of RFRA. The new order, said the dissenters, "evinces disregard for even the newest of this Court's precedents and undermines confidence in this institution."[20] Instead it might be read as undermining these justices' interpretation of what the Court said in *Hobby Lobby*.

As cases challenging the accommodation will not be considered by the Supreme Court until its October 2014 term, it seems clear that this dispute will continue well into next year, in politics as well as in the courts.

A New Threat: The Reproductive Health Non-Discrimination Act

Perhaps anticipating that they may not receive a favorable decision from the Supreme Court in the *Hobby Lobby* case, pro-abortion groups have been working for some time to develop statutory proposals to prevent faith-based groups from operating in harmony with their own moral and religious convictions on "reproductive" issues.

One product of this effort is the Reproductive Health Non-Discrimination Act, promoted by the National Women's Law Center (NWLC) and other pro-abortion groups. Legislation of this kind has been introduced thus far in New York, Michigan, North Carolina, and the District of Columbia.[21] The DC bill, for example, provides as follows:

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[18] *Little Sisters of the Poor v. Sebelius*, no. 13A691 (U.S. Jan. 24, 2014) (order granting the application for injunction).

[19] *Wheaton College v. Burwell*, no. 13A1284 (U.S. July 3, 2014) (order granting the application for injunction) (Scalia, J., concurring in the result).

[20] *Wheaton College v. Burwell* at 4 (Sotomayor, J., dissenting).

[21] The NWLC's testimony in Washington, DC, provides supporters' rationale for the legislation and includes citations to the similar bills introduced in three states. See Testimony

> An employer or employment agency shall not discriminate against an individual with respect to compensation, terms, conditions, or privileges of employment because of or on the basis of the individual's or a dependent's reproductive health decision making, including a decision to use or access a particular drug, device or medical service, because of or on the basis of an employer's personal beliefs about such services.[22]

The legislation includes no religious exemption, instead specifically stating that an employer's "personal beliefs" may *not* be a basis for making employment decisions. Policies of Catholic and other religious institutions, by which they seek to ensure that employees advance and do not undermine their religious mission, are cited by the NWLC and other supporting organizations as the chief examples demonstrating a need for this legal prohibition.

At a June 23 hearing before the DC City Council's Committee on the Judiciary and Public Safety, testimony against the bill was presented by the DC Catholic Conference and by the Alliance Defending Freedom, with ADF representing itself and seven other national pro-life organizations based in Washington. Leaders of the eight groups represented by ADF wrote to the committee's chairman before the hearing, saying that this bill "would punish pro-life employers, including the nonprofit organizations who make their home in the District, serve and employ its residents, and work to encourage respect for the sanctity of human life in our nation's capital." They argued that the bill "is unconstitutional and a patent violation of the Religious Freedom Restoration Act," and observed,

> Just as a nonprofit organization supporting abortion might believe it necessary to ensure that its employees were not participating in the March for Life or other pro-life activism, or an organization advocating for veganism might believe its message cannot be effectively communicated by someone who eats meat, a pro-life organization must be free to choose to expend its resources to employ those whose words and actions uphold and do not detract from the organization's mission.[23]

The United States Conference of Catholic Bishops submitted a written statement citing the DC Catholic Conference's testimony and adding its own concerned voice as a national religious organization headquartered in the District.[24]

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of Gretchen Borchelt, Senior Counsel and Director of State Reproductive Health Policy, National Women's Law Center, before the Council of the District of Columbia Committee on the Judiciary and Public Safety, June 23, 2014, http://www.nwlc.org/sites/default/files/pdfs/nwlc_dc_repro_non-discrimination_act_testimony_final.pdf .

[22] Reproductive Health Non-Discrimination Amendment Act of 2014, May 6, 2014, on the website of prime sponsor David Grosso, https://matt-grosso.squarespace.com/grosso-analysis/2014/5/6/reproductive-health-non-discrimination-amendment-act-of-2014. The DC proposal is titled an Amendment Act because it would become a new amendment to the District's Human Rights Act.

[23] M. Casey Mattox et al. to the Honorable Tommy Wells (chairperson, Committee on the Judiciary and Public Safety, Council of the District of Columbia), June 20, 2014, http://www.adfmedia.org/files/DCHealthLetter.pdf.

[24] Anthony R. Picarello to the Committee on the Judiciary and Public Safety, July 2, 2014, http://www.usccb.org/issues-and-action/religious-liberty/conscience-protection/

The legislation nevertheless seems to enjoy wide support on the DC council, and a similar bill has been approved by New York's state assembly (though it seems the state senate will not consider it this year).[25] If passed in any locality, such legislation is sure to produce a new wave of conflict and litigation over the right of pro-life organizations, both secular and religious, to operate in accord with their own deepest convictions about life and procreation.

The FDA Looks at "Three-Parent Embryos"

The federal government's advisors have begun to venture into the age of "designer" children, through a discussion of what news media have called the creation of "three-parent embryos." In this procedure, a healthy unfertilized egg *or* an already fertilized live embryo is destroyed so that its cell mass can be prepared to receive the nucleus of an egg or embryo produced by someone who has inheritable mitochondrial disease. Because the disease arises from faulty DNA in the cell mass but not in the nucleus, the theory is that transferring the nucleus to another egg or embryo could allow a woman with the condition to have a healthy and genetically related child.

News reports already speak of this as a kind of "cure" for mitochondrial disease. But it is more accurately described as the engineered creation of a new hybrid human being, using parts from two others. The resulting human being would have genetic material from one father and two mothers. As ethicist Jeffrey Kahn of Johns Hopkins University notes, "We're not treating humans. We're creating humans. There's not a model for that."[26]

Because the new hybrid genetic constitution could be passed on to future generations, it is also an instance of germ-line genetic engineering, which scientific and legal bodies throughout the world have rejected until now as being too fraught with incalculable and uncontrollable risks to the human species. Raising serious concerns about "three-parent embryo" trials last year, for example, the Council for Responsible Genetics noted that such modification of the human genome has been rejected by the United Nations and the Council of Europe.[27]

Nevertheless, some US researchers have applied for approval from the Food and Drug Administration to pursue clinical trials, and an advisory committee of the FDA has been meeting to discuss the medical benefits and risks of granting such approval. In its briefing document for the advisory committee's meeting of February 25–26, the FDA notes that "ethical and social policy issues related to genetic modification

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[25] See New York State Assembly, "Assembly Passes Legislation Prohibiting Employers from Discriminating against an Employee's Reproductive Health Decisions," news release, June 18, 2014, http://assembly.state.ny.us/Press/20140618c/.

[26] Gretchen Vogel, "FDA Considers Trials of 'Three-Parent Embryos,'" *Science* 343.6173 (February 21, 2014): 828.

[27] Council for Responsible Genetics, comments submitted to the FDA Cellular, Tissue ,and Gene Therapies Advisory Committee (October 15, 2013), 5, http://www.councilforresponsiblegenetics.org/pageDocuments/1USSWUKK5Y.pdf.

of eggs and embryos" are "outside the scope of this meeting."[28] The document does not explain who *does* have responsibility for worrying about these issues. But the medical concerns cited in this document are harrowing enough, and some proposals for addressing those concerns raise their own serious ethical problems.

The FDA briefing document outlines several ways in which such trials could pose risks to both mother and child, in addition to the risks ordinarily created by in vitro fertilization (IVF). For example, a child created in this way may still develop mitochondrial disease, and may be harmed by the "mismatch" between nuclear and mitochondrial DNA, the manipulation procedure itself, or the toxicity of the reagents used.[29] The epigenetic abnormalities created by the "mismatch" problem may not manifest themselves until well after birth.[30]

These concerns are multiplied by the realization that such abnormalities may then be carried on to the child's future offspring and enter the human gene pool generally. The FDA document mentions two ways of trying to minimize that prospect. One is to conduct preimplantation genetic diagnosis on all embryos created by this means, although with current technology this will be very unreliable for detecting these genetic and epigenetic problems; presumably any evidence of problems would lead to discarding embryos before transfer to a womb. The document notes in this context that because these procedures will produce "significant numbers of eggs that fail to fertilize and embryos that develop abnormally," the number of (apparently) normal embryos transferred to a womb will have to be "sufficiently high to provide a reasonable expectation of producing viable offspring."[31]

The other proposal for preventing germ-line abnormalities is straightforward enough: Because such mitochondrial defects are passed down from the mother, simply discard all female embryos resulting from these procedures, "selecting only male embryos for transfer."[32] And to think that when religious organizations object to providing drugs that can attack human embryonic life through their health coverage, it is they who are accused of waging a "war on women."

While this avenue is surely open to criticism even as a means for trying to prevent debilitating mitochondrial disease, the researchers applying for FDA approval also propose using it to replace women's aging mitochondria as a treatment for age-related infertility. Even at the outset, then, this risky protocol, involving the destruction of untold numbers of nascent human lives, is being proposed not only for addressing disease but also for serving the desires of people who want to avoid the

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[28] Cellular, Tissue, and Gene Therapies Advisory Committee, *Oocyte Modification in Assisted Reproduction for the Prevention of Transmission of Mitochondrial Disease or Treatment of Infertility* (meeting 59, February 25–26, 2014), FDA briefing document, 4, http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/BloodVaccinesandOtherBiologics/CellularTissueandGeneTherapiesAdvisoryCommittee/UCM385461.pdf.

[29] Ibid., 18.

[30] Ibid.

[31] Ibid., 16.

[32] Ibid., 21; see also 7 (where this is called "incorporating gender selection as a safety measure") and 23.

natural consequences of aging. Commentators say this "would widen the potential pool of patients to include millions of women." Jeffrey Kahn observes, "Once it's used, it will be used in all sorts of ways for all sorts of people. That's the reality of this kind of medicine."[33]

The FDA advisory committee members in late February seemed skeptical about allowing clinical trials to proceed in the near future. Their caution was not shared by all commentators. Responding to concerns about the germ-line genetic manipulation proposed here, prominent bioethicist Arthur Caplan said, "I understand the concern about where we might go. I'm going to worry about that when I get there."[34]

Fifteen years ago, Christian ethicist Nigel Cameron used to say that our society's bioethical debates would move from taking life (e.g., through abortion and euthanasia) to making life (through cloning and genetic modification) and to faking life (through advances ranging from artificial chromosomes to artificial intelligence). We are now well into the age of proposals for making life, some of which could involve a great deal of taking life as well.

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[33] See Vogel, "FDA Considers Three-Parent Embryos," 827.

[34] Quoted in Jonathan Imbody, "Debate over Three-Parent Embryos and DNA Manipulation Reveals Baseless 'Bioethics,'" *Freedom2Care* (blog), February 27, 2014, http://freedom2care.blogspot.com/2014/02/debate-over-three-parent-embryos-and.html.