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The spring and early summer of 2013 saw continued debate on whether rights of religious freedom can stand against sweeping federal mandates for contraceptive coverage. New developments included a landmark US Supreme Court decision on whether human genes can be patented, and a long-awaited scientific "advance" in human cloning that may revive congressional debates on embryonic stem cell research.

The HHS Mandate and Conscience Rights

Congressional, judicial, and regulatory debates continue on the Obama administration's mandate that almost all health plans cover female sterilization, the full range of drugs and devices approved by the FDA for contraception (including some that can cause an abortion), and related "education and counseling" for women and girls. As noted in previous columns, the outcome of this debate may well determine whether the federal government has authority to force individuals and institutions to be involved in other controversial bioethics procedures—as a condition for receiving government grants and other benefits or simply for taking part in health care and other areas of public life.

There are now sixty-four lawsuits against the mandate, filed by both nonprofit and for-profit organizations, for a total of over two hundred plaintiffs.[1] And in twenty-three of thirty decisions, for-profit businesses seeking temporary relief from the mandate while litigation continues have obtained that relief from federal courts.

Perhaps the most important of these decisions was handed down near the end of June by the Tenth Circuit Court of Appeals. The largest Christian-owned business

[1] As noted in previous columns, information and updates on these cases can be found at the HHS Mandate Information Central site maintained by the Becket Fund for Religious Liberty, http://www.becketfund.org/hhsinformationcentral/.

involved in these law suits, Hobby Lobby—with over thirteen thousand employees and five hundred stores in forty-one states—had been denied relief by a U.S. district court and had failed in its effort to obtain emergency relief from the Supreme Court. But on June 27, in an *en banc* decision, the Tenth Circuit found that Hobby Lobby had "established a likely violation of RFRA [Religious Freedom Restoration Act]" by the administration and had shown that it could suffer "irreparable harm" if relief were not granted.[2] This was a last-minute reprieve for Hobby Lobby, which could have faced crippling fines and other penalties beginning July 1. The case was remanded to the federal trial court, which ultimately granted a preliminary injunction on July 19.

The Tenth Circuit's lengthy opinion, the first definitive ruling by a federal appellate court on the administration's case against religious freedom for business owners, strongly rebuffs the argument that a for-profit business owned by religious believers cannot enjoy the fundamental right to free exercise of religion. The administration had argued that the First Amendment and the Religious Freedom Restoration Act protect the religious freedom only of "persons," and that the term "persons" does not include for-profit corporations. After reviewing judicial precedents, however, the Tenth Circuit said that "the government has given us no persuasive reason to think that Congress meant 'person' in RFRA to mean anything other than its default meaning in the Dictionary Act—which includes corporations regardless of their profit-making status."[3] The court noted Supreme Court precedents establishing that the First Amendment's guarantee of free exercise of religion can belong to corporations as well as individuals, and to individuals involved in for-profit pursuits such as kosher businesses—and that other First Amendment rights, such as freedom of political speech, can also belong to a for-profit corporation.[4]

In another landmark decision, a US district court in Pennsylvania granted a preliminary injunction to Geneva College, a nonprofit Christian institution of higher learning whose religious tenets forbid providing student health insurance for potentially abortifacient drugs and devices such as Ella (ulipristal acetate), IUDs, and Plan B (levonorgestrel).

Most lawsuits brought by nonprofit religious institutions have thus far been dismissed without prejudice by federal courts, on the basis of the administration's argument that its rule governing such institutions was not yet finalized and in any

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[2] *Hobby Lobby Stores, Inc. v. Sebelius*, no. 12–6294 (10th Cir. June 27, 2013), slip op., 65. An *en banc* decision involves all members of a circuit court rather than the usual three-judge panel. In this case, one member recused himself, leaving eight members. Four of these would have granted Hobby Lobby an injunction outright; a fifth joined a majority opinion rebutting the district court's analysis but thought the case should be remanded to the lower court for further proceedings, as that court had not addressed all relevant factors for granting an injunction when it denied Hobby Lobby's request.

[3] Ibid., 34–35.

[4] A key Supreme Court ruling here is *Citizens United v. FEC*, 558 U.S. 310 (2010), invalidating a provision of federal campaign finance law that was found to limit the freedom of political speech of corporations. The five justices joining in the court's opinion on this point, including author Anthony Kennedy, remain on the court; one dissenting justice, John Paul Stevens, has since been replaced by Elena Kagan.

case would not take effect until at least August 1. The court rejected that argument in this case, because Geneva College had to negotiate a student health plan for the new school year by July 1 and would drop the health plan altogether if it was forced to provide abortifacients. The court found a likelihood of success on the merits on the part of Geneva College. It also said that the administration has fatally undermined its own argument that a compelling governmental interest in public health requires it to override religious freedom since it has exempted "grandfathered" health plans, which cover 191 million Americans, and has granted many other exceptions to the mandate.

The administration released its final rule governing nonprofit religious institutions on June 28, so other suits by nonprofit religious institutions subjected to the mandate are now expected to revive.[5] An official from the Department of Health and Human Services said the final rule is "very similar" to the proposed rule the administration published for public comment in February 2013. Eric Rassbach of the Becket Fund for Religious Liberty agreed, saying the final rule is "the same old, same old." He added that the rule "doesn't solve the religious conscience problem because it still makes our nonprofit clients the gatekeepers to abortion and provides no protection to religious businesses."[6]

Initially, Cardinal Timothy Dolan, president of the United States Conference of Catholic Bishops, said the long and complex final rule (110 pages in manuscript form) required careful study, but he welcomed the administration's announcement that the rule will not be applied to nonprofit religious institutions until January 1, 2014 (instead of August 1, 2013). On July 3, he issued a more substantive statement, reviewing how the final rule treats three kinds of organizations with a religious objection to some or all of the contraceptive mandate.[7]

First, he said, there is no change in the rule's incredibly narrow definition of "religious employer," which allows a genuine exemption from the mandate chiefly for "houses of worship" and their integrated auxiliaries. Second, at the other end of the spectrum, there is no change in the administration's decision to apply the mandate with full force to individuals and for-profit employers.[8]

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[5] The final rule was published in the *Federal Register* a few days later. See "Coverage of Certain Preventive Services under the Affordable Care Act," final rule, 78 Fed. Reg. 39870–39899 (July 2, 2013).

[6] Becket Fund for Religious Liberty, "Final HHS Rule Fails to Protect Constitutional Rights of Millions of Americans," news release, June 28, 2013, http://www.becketfund.org/becket-welcomes-opportunity-to-study-final-rule-on-hhs-mandate/.

[7] See US Conference of Catholic Bishops, "Cardinal Dolan: Latest HHS Rule Being Studied, Time Extension Appreciated," news release, June 28, 2013, http://usccb.org/news/2013/13–131.cfm; and "HHS Final Rule Still Requires Action in Congress, by Courts, Says Cardinal Dolan," news release, July 3, 2013, http://usccb.org/news/2013/13–137.cfm.

[8] For that matter, the final rule (like earlier versions) makes no accommodation for nonprofit organizations, such as pro-life groups, that are not explicitly religious. These groups may have a strong moral objection to the inclusion of drugs and devices that can cause an abortion.

For an intermediate class of organizations—those nonprofit religious organizations, such as schools, charities, and hospitals, that do not qualify for the religious exemption but are being offered an "accommodation"—Cardinal Dolan said, "The overall structure remains the same as under the proposed rule" of February 2013, which the USCCB had strongly criticized.[9] However, there are three "relatively small changes" to the accommodation that will "take more time to evaluate." These changes (with some additional commentary by this author) are as follows:

First, the proposed rule said that in cases where the objecting religious organization purchases its health plan from an insurer, the insurer would provide access to "free" contraceptives by "automatically" issuing a separate "contraceptive-only" policy to all the organization's employees and their beneficiaries. The final rule now says there will be no separate policy. Rather, the insurer will write to all enrollees in the employer's plan, assuring them that if they (or their beneficiaries) access any of the drugs, devices, or procedures to which the employer objects, the insurer will nevertheless provide "payments" covering their full cost.

One might ask what practical difference there is between "automatic" contraceptive *coverage*, and a written pledge that the insurance company will automatically pay for contraceptives. The key legal difference for the administration seems to be that its earlier offer of a separate "contraceptive-only" health plan may conflict with state laws that require all health plans to include a range of minimum benefits.[10] By calling these outlays "payments" rather than "coverage," the administration hopes to evade this problem. Another possible advantage from the administration's viewpoint is that if these payments do not amount to "coverage" under a health benefits plan, perhaps payments for contraceptives and sterilizations obtained clandestinely by minor girls will not have to show up on their parents' insurance claims report at the end of the month. In any case, this abandonment of the "separate policy" approach may only exacerbate the moral problem for employers. "Now," notes Cardinal Dolan, "there is only one policy, and it is the one sponsored by the Catholic employer," and objectionable items "will still be paid for by virtue of the fact that an employee belongs to the Catholic employer's plan."

The second change is that an assurance has been added that insurers will keep any funds for contraceptive items "separate" from money paid to them by religious organizations and their employees through premiums. This is designed to underscore the argument that those who object to these items will not be required in any way to

[9] See Office of the General Counsel, US Conference of Catholic Bishops, to Centers for Medicare and Medicaid Services, Department of Health and Human Services, "Notice of Proposed Rulemaking on Preventive Services," letter, March 20, 2013, http://www.usccb.org/about/general-counsel/rulemaking/upload/2013-NPRM-Comments-3–20-final.pdf.

[10] That offer also conflicted with a similar requirement in the federal Affordable Care Act itself—except that the ACA had exempted certain narrow types of plans like those offered for vision or dental coverage from the "all essential health benefits" requirement, and had authorized the Department of Health and Human Services to add to this list of exempted plans. The proposed rule had a provision exempting "contraceptive-only" plans from this requirement; that provision is dropped from the final rule.

subsidize them. The problems begin when the administration tries to explain where this "separate" money will be found.

For example, says the final rule, "issuers reasonably could set the premium for an eligible organization's large group policy as if no payments for contraceptive services had been provided to plan participants and beneficiaries—reflecting the actual terms of the group policy, which expressly excludes contraceptive coverage."[11] The assumption here seems to be that the religious organization's employees will have fewer live births (and fewer other adverse conditions that unintended pregnancy supposedly causes), but the insurer can keep charging the organization the same premium amount as in the past when there were more live births, and the resulting overcharge can recompense the insurer for contraceptive services. This hardly seems to keep the funds "separate," since contraceptives would be subsidized with the premium dollars the organization and its employees have been paying for maternity care.

A second option is for the insurer "to treat the cost of payments for contraceptive services for women enrolled in insured group health plans established or maintained by eligible organizations as an administrative cost that is spread across the issuer's entire risk pool, excluding plans established or maintained by eligible organizations."[12] The administration claims that the price of this cost-shifting to other health plans would be "negligible and effectively cost neutral to issuers," and cites an HHS document that claims contraceptive coverage is "cost neutral." However, the claim of "cost neutrality" in that paper is based on the assumption that the cost of contraceptives is offset by money saved from reduced childbirths in the same plan—exactly the mixing of funds that the administration wants to claim it will avoid here. So the claim of a source of payments that is both workable and truly separate seems to travel in circles. And remarkably, the idea of cost-shifting to an insurer's "entire risk pool," except for employers eligible for the "accommodation," suggests that even insurance-purchasing houses of worship, which are supposed to be entirely exempt, could end up helping to pay for the objectionable coverage for employees of "accommodated" religious organizations.

The third change relates to "self-insured" plans, where an employer does not purchase a health plan from an insurance company but designs its own plan and hires a third-party administrator (TPA) to manage and pay claims. The proposed rule had struggled with three different ways to work out the TPA's role in administering objectionable coverage, since ordinarily a TPA has no right under federal insurance law (ERISA) to administer anything except what its client, in this case the religious organization, has designated it to administer in the "instrument" governing its contract. Catholic organizations such as the USCCB and Catholic Health Association had identified one of the three options as imposing the least oppressive burden on religious freedom. The administration instead has chosen to finalize the option that was described by Cardinal Dolan as "the most objectionable of the three."

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[11] Final rule, 39877.

[12] Ibid., 39878. "Eligible organization" is a technical term used in the final rule to describe nonprofit religious groups that are not exempt from the mandate but are offered the "accommodation."

Under this approach, when the religious organization files the required "self-certification" document stating its religious objection to some or all contraceptive items, that document "will afford the third party administrator notice of obligations set forth in these final regulations, and *will be treated as a designation of the third party administrator(s) as plan administrator and claims administrator for contraceptive benefits* pursuant to section 3(16) of ERISA."[13] So by the very act of filing its objection, the religious organization will legally empower the TPA to do exactly what is contrary to the organization's religious convictions—and it will know in advance that this is the primary legal effect of filing its objection. (If it does not file the objection, of course, it will be subject to the requirement that it directly provide coverage for all objectionable items.)

In short, these changes do not adequately address the objections raised by numerous religious organizations to the proposed rule of February 2013, and some of them seem to make things significantly worse. Cardinal Dolan therefore concluded his statement by noting that at this point "our study has not discovered any new change that eliminates the need to continue defending our rights in Congress and the courts."

A similar message was communicated the previous day by Archbishop William E. Lori of Baltimore, chair of the US bishops' Ad Hoc Committee for Religious Liberty, who said the USCCB "will continue to seek relief from the courts and from Congress as appropriate." He was speaking at a July 2 press conference announcing the release of an open letter to all Americans, signed by more than a hundred religious leaders and scholars from diverse backgrounds, including the Southern Baptist Convention, the Church of Jesus Christ of Latter-day Saints, the International Society for Krishna Consciousness, Orthodox Christian churches, and Judaism. The letter, "Standing Together for Religious Freedom," declares,

> Many of the signatories on this letter do not hold doctrinal objections to the use of contraception. Yet we stand united in protest to this mandate, recognizing the encroachment on the conscience of our fellow citizens. Whether or not we agree with the particular conscientious objection is beside the point. HHS continues to deny many Americans the freedom to manifest their beliefs through practice and observance in their daily lives.[14]

Mentioned by Archbishop Lori at the press conference was pending legislation in Congress called the Health Care Conscience Rights Act (H. R. 940), sponsored by Rep. Diane Black (R-TN) and, at this writing, a bipartisan group of 182 other House members. This bill would improve current federal protections for conscientious objection to abortion, and forbid the government to impose the new mandates created by the Affordable Care Act when individuals or organizations have a moral or religious objection to abortion or other specific items or procedures. On June 20, an identical Senate companion bill, S. 1204, was introduced by Senators Tom Coburn (R-OK) and Deb Fischer (R-NE). The delayed date for imposing the HHS mandate

[13] Ibid., 39879, emphasis added.

[14] US Conference of Catholic Bishops, "Catholic, Southern Baptist Religious Liberty Leaders Lead Open Letter Effort for Conscience Protection Given HHS Mandate," news release, July 2, 2013. The text of the letter is available at http://usccb.org/news/2013/13–134.cfm, along with links to the statements and biographies of press conference participants.

on religious nonprofits gives this legislation more time to gather additional cosponsors and other support.

HHS Drops Limits on Over-the-Counter Sale of Plan B One-Step to Children

As reported in the Spring 2013 issue of this journal,[15] a federal district judge on April 5 ordered the Food and Drug Administration to drop its age restrictions on over-the-counter access to Plan B One-Step, a one-dose version of the "emergency contraception" drug levonorgestrel. U.S. District Judge Edward Korman said HHS Secretary Kathleen Sebelius's 2011 decision to allow OTC access only for those aged seventeen and over was "arbitrary, capricious, and unreasonable." Initially, HHS said it would appeal this decision, and it approved a compromise proposal from the drug's manufacturer to allow such non-prescription access for children aged fifteen and over. But on June 10, 2013, HHS announced that it was complying with the judge's original order to drop all age restrictions. An FDA official took this opportunity to declare, "Over-the-counter access to emergency contraceptive products has the potential to further decrease the rate of unintended pregnancies in the United States."[16]

The FDA's declaration is contrary to the evidence. For example, in 2007, enthusiastic supporters of Plan B at Princeton University conducted an analysis of twenty-three different studies gauging the effect of programs expanding access to such drugs—including efforts to make them more easily available to adolescents over-the-counter. Not one of the studies could find a statistically significant reduction in unintended pregnancies or abortions.[17] In 2011, the Association of Reproductive Health Professionals confirmed that this remains true: "*No* published study has demonstrated that increasing access to emergency contraception pills (ECPs) reduces pregnancy or abortion rates at the population level, although one demonstration project and three clinical trials were specifically designed to address this issue."[18] Other studies suggest that increased access to emergency contraceptives can *increase* the incidence of sexually transmitted diseases among young people.[19]

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[15] T. Davis, "A Judge's Flawed Understanding of How Levonorgestrel Works," letter, *National Catholic Bioethics Quarterly* 13.1 (Spring 2013): 10–14.

[16] See M. Castillo, "FDA Approves Over-the-Counter Sales of Plan B One-Step for All Ages," *CBS News*, June 20, 2013, http://www.cbsnews.com/8301–204_162–57590358/fda-approves-over-the-counter-sales-of-plan-b-one-step-for-all-ages/.

[17] E. Raymond et al., "Population Effect of Increased Access to Emergency Contraceptive Pills: A Systematic Review," *Obstetrics and Gynecology* 109 (2007): 181–8.

[18] Association of Reproductive Health Professionals, "Impact of EC on Unintended Pregnancy: Population Level," *Update on Emergency Contraception* (March 2011), http://www.arhp.org/Publications-and-Resources/Clinical-Proceedings/EC/Population-Level, emphasis added.

[19] S. Girma and D. Paton, "The Impact of Emergency Birth Control on Teen Pregnancy and STIs," *Journal of Health Economics* 30.2 (March 2011): 373–380. For a review of findings on the effects of increased access to emergency contraception, see US Conference of Catholic Bishops, "Emergency Contraception Fails to Reduce Unintended Pregnancy and Abortion," fact sheet (April 6, 2011), http://usccb.org/issues-and-action/human-life

Judge Korman's decision also recommended that the FDA and the drug's manufacturer remove from their materials any suggestion that Plan B might prevent embryo implantation—although there is no consensus on that point, and recent scientific findings continue to raise the possibility that the prevention of implantation is a mechanism of action of the drug.[20]

The successful drive to give children of all ages unlimited access to Plan B was hailed in some quarters as a victory of science (the FDA and Judge Korman) over politics (the initial hesitations of Secretary Sebelius). The truth is the opposite. A more accurate scientific assessment would be that this powerful drug's medical safety for young minors is, at best, unknown; that wider access has no significant role in reducing pregnancy, and may increase premature sexual activity and attendant serious diseases; that Plan B might also act in a way that is abortive; and that driving young teens and preteens into greater isolation from the loving care and supervision of their parents on matters of health care and sexuality is harmful to them and to society. As noted above, the administration also plans to ensure that teens obtain "free" access to such drugs without parents' supervision through the health plans of those parents—accompanied by free "education and counseling" indoctrinating them in what now passes for science among those who are committed to a particular version of reproductive politics.

Supreme Court Says No to Human Gene Patenting

The Supreme Court's June 13 decision on human gene patenting has answered, at least for the time being, a question that has bedeviled scientists, biotechnology companies, and other courts: can a company that has discovered important facts about a human gene, a naturally occurring part of a human being, actually take out a patent on the gene itself?

The case involved Myriad Genetics, which has discovered "the precise location and sequence" of the BRCA1 and BRCA2 genes. Mutations of these genes can dramatically increase women's risk of developing breast cancer and ovarian cancer. A company that could patent these genes would have exclusive rights to isolate them in individuals, giving it an effective monopoly on testing for this genetic predisposition for cancer.

A US district court had ruled that Myriad Genetics could patent neither the naturally occurring genes nor a synthetically created DNA called "complementary

-and-dignity/contraception/fact-sheets/emergency-contraception-fails-to-reduce-unintended-pregnancy-abortion.cfm.

[20] See, for example, B. Mozzanega and E. Cosmi, "How Do Levonorgestrel-Only Emergency Contraceptive Pills Prevent Pregnancy? Some Considerations," *Gynecological Endocrinology* 27.6 (June 2011): 439–442, abstract at http://www.ncbi.nlm.nih.gov/pubmed/20670097; and C. Valenzuela, "Postovulatory Effects of Levonorgestrel Used for Emergency Contraception. Is It Abortive?," *International Journal of Medical and Biological Frontiers* 17.7 (2011): 667–674, https://www.novapublishers.com/catalog/product_info.php?products_id=26686.

DNA" (cDNA) that contains only protein-coding information from those genes. The Federal Circuit Court of Appeals reversed that decision, ruling that Myriad could patent both the naturally occurring genes and their synthetic counterparts. The Supreme Court divided the question, ruling that the synthetically altered DNA strands could be patented but not the genes as they naturally occur in the human body.

Justice Clarence Thomas wrote the opinion for a unanimous court, except that Justice Antonin Scalia declined to endorse some parts of the opinion that dealt with "fine details of molecular biology" with which he is unfamiliar. Along with the other eight justices, however, he was persuaded of the legally decisive distinction between isolating a gene as it occurs in nature and inventing a modified counterpart that is not present in nature. As Justice Thomas said in his opinion, "Myriad did not create anything. To be sure, it found an important and useful gene, but separating that gene from its surrounding genetic material is not an act of invention."[21]

Physicians and activists committed to expanding patients' access to testing for breast cancer risk hailed the decision. Others will puzzle over its implications for some time to come, as an age of genetic engineering, artificial chromosomes, and reproductive technology increasingly tries to blur the line between natural phenomena and man-made creations. As one sign of the complexity of the issue, the court's opinion briefly mentioned a rider to the Consolidated Appropriations Act of 2004 (later adapted to become part of permanent patenting law) that states, "None of the funds appropriated or otherwise made available under this Act may be used to issue patents on claims directed to or encompassing a human organism." The rider was sponsored by pro-life members of Congress to head off any attempts at patenting cloned or genetically engineered human embryos. It had been opposed by the Biotechnology Industry Organization (BIO), which claimed that researchers should be able to *patent* a human embryo whose traits they have engineered, because such an altered embryo is not a "product of nature." The 2004 rider was cited by Myriad Genetics (unsuccessfully) in support of *its* position,[22] apparently to claim that a gene should be patentable because it is not a full "organism."

New Advance (?) in Human Cloning

Policy debate on human embryonic stem cell research has been linked for fifteen years with debates on human cloning. Scientists have said that embryonic stem cells will have very limited potential for clinical use unless a way can be found to produce genetically individualized stem cells for each patient, solving the problem of immune rejection. Cloning by somatic cell nuclear transfer (SCNT) has been proposed as an answer. The nuclear genetic material from a person's body cell ("somatic cell") is inserted into an unfertilized egg whose own nuclear material has been removed or rendered inert; the resulting cell is stimulated to begin development as a human embryo that is the original person's genetic twin. This cloned human embryo could then be destroyed for its genetically tailored embryonic stem cells.

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[21] *Association for Molecular Pathology v. Myriad Genetics*, 569 U.S. ___ (2013), slip op., 12.

[22] Ibid., 15–16.

Such cloning efforts have labored under two serious burdens for many years. First, even many people who defend use of "spare" or "excess" embryos from fertility clinics for embryonic stem cell research have been repulsed by the idea of specially creating human embryos in the laboratory solely in order to destroy them. Second, researchers have failed again and again to make this approach work, and some of those failures also involved fraudulent claims of success. The most highly visible fraud was perpetrated in 2005 by a South Korean team led by Dr. Woo Suk Hwang. When this research was found to involve grossly unethical practices (e.g., fabricating data and soliciting and paying women to provide eggs for the research, at risk to their own health) and to have failed to produce cloned embryos, let alone any embryonic stem cell lines, support for cloning was set back years.

In May 2013, however, a research team led by Dr. Shoukhrat Mitalipov of the Oregon Health and Science University may finally have succeeded in producing cloned human embryos and obtaining embryonic stem cell lines from them.[23] The policy implications of this news include the following:

First, the researchers have modified and refined the SCNT cloning process to the point where it may actually be a feasible approach to obtaining embryonic stem cells with a particular genetic profile. Altogether they required 122 cloned embryos to produce six embryonic stem cell lines (and four of those lines used fetal skin cells for their genetic material). But the efficiency of the process increased to the point where, in their final stage of research, the scientists could boast of creating a cell line beginning with only two donated oocytes.

Second, the ethical concern about persuading women to "donate" (or rather sell) their eggs for this process, with attendant health risks for the women, remains. Human eggs in this study were obtained from women using "standard ovarian stimulation protocols," which have been shown to pose some risks of infertility, serious illness, and even death for donors. Researchers found that success in cloning "is dependent on human oocyte quality," and they hailed the "exceptional oocyte quality from one donor," whose eggs were used to produce the embryos that led to four of the six embryonic stem cell lines. The researchers think less optimal sources, like eggs matured in the laboratory after being obtained from (born or unborn) cadavers, will not be effective. So one can expect protocols for soliciting and paying "exceptional quality" egg donors for such research, as donors may be needed in the thousands or hundreds of thousands if the goal of therapeutic use for these cells is ever realized. Already California, where some scientists are eager to pursue cloning experiments,

[23] M. Tachibana et al., "Human Embryonic Stem Cells Derived by Somatic Cell Nuclear Transfer," *Cell* 153.6 (June 6, 2013): 1228–1238. Even this study was questioned when several errors, including mislabeled or duplicated graphics, were detected. The authors said that these were "innocent mistakes" that do not affect the results of the study. Critics blame the errors on the authors' and editors' "unfathomably rapid rush to publication." See D. Cyranoski and E. Hayden, "Stem-Cell Cloner Acknowledges Errors in Groundbreaking Paper," *Nature News*, May 23, 2013, http://www.nature.com/news/stem-cell-cloner-acknowledges-errors-in-groundbreaking-paper-1.13060.

is preparing to drop current legal limits on payments to women who provide eggs for research.[24]

Third, this study brings closer the day when researchers will produce cloned babies, a prospect that most Americans strongly oppose. While the Oregon researchers and others initially tried to dismiss this prospect of so-called reproductive cloning, it follows inevitably from the researchers' success in producing normal blastocyst-stage embryos. In fact, some of those same researchers reported in 2010 that they had already established several pregnancies in nonhuman primates using SCNT embryos, though none had yet survived to term.[25] To someone not bound by moral qualms about such egregious manipulation of human life, or by legal prohibitions, the remaining barriers to producing live-born cloned children seem to be technical barriers that are solvable in principle.

Despite the far-reaching implications of the new study, it received little public attention compared to past (misleading) announcements about success in human cloning. While this may partly be due to greater caution on the part of news media that have been taken in by such announcements in the past, it was also due to two other factors.

First, the researchers themselves and those who initially reported the news simply obscured what had been done by describing the study as involving the use of cloning to create "stem cells" (instead of creating human embryos that were then destroyed for their stem cells).[26] This invited confusion between the new study and the Nobel Prize–winning breakthrough by Dr. Shinya Yamanaka, who developed a method for directly reprogramming adult human cells into embryonic-like stem cells, called "induced pluripotent stem cells" (iPS cells), in 2007. The use of iPS cells has developed rapidly since Dr. Yamanaka's discovery, not least because his approach avoids all moral concerns about creating and destroying embryos. To those who believed that only "stem cells" had been created from body cells, it was difficult to figure out what was new in the Oregon study. What was new was that the older, much more ethically problematic effort to create and destroy cloned embryos is reasserting itself.

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[24] C. Schubert, "California Bill Poised to Lift Restrictions on Egg Donation," *Nature News*, June 18, 2013, http://www.nature.com/news/california-bill-poised-to-lift-restrictions-on-egg-donation-1.13218. This article notes that the women who provided eggs for the cloning study in Oregon were paid $3,000 to $7,000 each.

[25] "Reproductive cloning of nonhuman primates by SCNT has not been achieved yet. We have been able to establish several pregnancies with SCNT embryos which, *so far*, did not progress to term." M. Sparman et al., "Cloning of Non-human Primates: The Road 'Less Traveled by,'" *International Journal of Developmental Biology* 54.11–12 (2010): 1671, emphasis added, http://www.ijdb.ehu.es/web/paper.php?doi=10.1387/ijdb.103196ms.

[26] For example, the study's own title refers to "human embryonic *stem cells* derived by somatic cell nuclear transfer," its abstract uses similar evasions, and a major news story about the study refers to the lead researcher as a "stem-cell cloner." See Tachibana et al., "Human Embryonic Stem Cells Derived by Somatic Cell Nuclear Transfer"; and Cyranoski and Hayden, "Stem-Cell Cloner Acknowledges Errors."

Second, once it was clear that the new announcement was about something different from and more controversial than iPS cells, scientists and others began to wonder whether the time for enthusiasm about cloning human embryos for embryonic stem cell research has come and gone. While the Oregon researchers claim that stem cells from cloning may have advantages over iPS and other cells, the reality is that iPS cells in recent years have advanced far more rapidly than embryonic stem cells in terms of disease research results, scientific attention, and private and public funding.[27] Even the California Institute for Regenerative Medicine (CIRM), created by ballot initiative in November 2004 with the mission of spending $3 billion over ten years to advance embryonic stem cell and cloning research, has turned the lion's share of its funding toward pursuing iPS and adult stem cell research in recent years—in a desperate effort to show clinical progress for its efforts before time and money run out.[28]

But the possible obsolescence of human cloning efforts has not deterred some researchers from insisting that they must be allowed to pursue any avenue that is of potential scientific and medical interest—including research using cloned human embryos and the stem cells derived from them. Some greeted the news from Oregon by complaining that the Obama administration's guidelines on embryonic stem cell research do not allow them to use federal funds to study the new cell lines—because those funds are reserved for research on embryonic stem cells from "spare" embryos from IVF clinics.[29] And Dr. Alan Trounson, CIRM's own president, has co-authored a manifesto to keep fellow researchers focused on the possible benefits of cloning and of "human embryo research" in general. In an apparent slap at the Oregon research team, Trounson warns his colleagues, "To ensure that rational discussion among scientists, policy-makers, regulators and the public precedes the formulation of regulatory policy, individual researchers should try to avoid confronting the public with controversial scientific leaps out of the blue. Instead, scientists should gather to discuss the present and future course of human embryo research. They should also help to establish a formal programme for public consultation," modeled on the process in the United Kingdom.[30]

Trounson essentially wants scientists to get together and chart the news of controversial developments, and help frame public response to them, before the general public is aware that they exist. He envisions a process in which groups like the National Academy of Sciences "lead the way" in negotiating ethical objections, teaming up with "patient advocate groups" focused on diseases like juvenile diabetes

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[27] See M. Cook, "Not with a Bang, But a Whimper," *MercatorNet*, May 31, 2013, http://www.mercatornet.com/articles/view/not_with_a_bang_but_a_whimper.

[28] G. Tarne, "New California Grants Once Again Bolster Ethical Stem Cell Alternatives," *Charlotte Lozier Institute*, April 18, 2013, http://www.lozierinstitute.org/new-california-grants-once-again-bolster-ethical-stem-cell-alternatives/.

[29] D. Cyranoski, "US Scientists Chafe at Restrictions on New Stem-Cell Lines," *Nature News*, June 4, 2013, http://www.nature.com/news/us-scientists-chafe-at-restrictions-on-new-stem-cell-lines-1.13114.

[30] M. Pera and A. Trounson, "Stem-Cell Researchers Must Stay Engaged," *Nature* 498.7453(June 13, 2013):159–161.

to channel the broader public debate toward appreciating the potential benefits of the research.[31] This seems to promise a repeat of the politicized and misleading hype that led so many voters, investors, and lawmakers to ignore moral concerns and expend huge amounts of time and money on embryonic stem cell research over the past fifteen years.

The first sign of this renewed political effort in the halls of Congress is the June 19 introduction of the Stem Cell Research Advancement Act of 2013 (H.R. 2433) by Reps. Diana DeGette (D-CO) and Charlie Dent (R-PA). Like similar bills in past years, the legislation presents itself as an effort to codify in law the guidelines of the Obama administration, which allow federally funded research only on embryonic stem cells derived from "spare" embryos created by IVF. However, the legislation includes an expansion clause allowing the secretary of HHS and the director of the NIH to review the guidelines at least every three years, and "update" them "as scientifically warranted." This seems to set the stage for funding research involving cloned human embryos in the future.

As if to confirm that suspicion, the only activity that the legislation clearly prohibits using federal funds is "human cloning," which is then defined as "the implantation" of the product of SCNT into "a uterus or the functional equivalent of a uterus." In other words, the sponsors seem to expect federal funding at a later date for creating cloned human embryos, destroying them, and doing research on the resulting stem cells, as long as efforts to bring cloned embryos to live birth are discouraged (or are conducted with private funds). Within a federally funded program, then, the only thing it would be illegal to do with a cloned human individual would be to allow him or her to survive past the embryonic stage.

Fortunately, this is not Congress's only model for placing "ethical limits" on this research. On May 23, Rep. Andy Harris (R-MD) reintroduced the Human Cloning Prohibition Act (H.R. 2164), a bill that would actually ban the use of the SCNT cloning procedure to create human embryos in the laboratory for any purpose. Similar legislation was approved by the House of Representatives in 2001 and 2003, but has never been approved by the Senate. The makeup of the current Congress is such that this impasse may well continue.

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[31] Ibid., 161.